The International Comparative Legal Guide to:

# Pharmaceutical Advertising 2019

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# Antitrust Issues in Pharma Pricing: A Snapshot

John Schmidt

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Ludovica Pizzetti

The pharmaceutical sector has in recent years been closely scrutinised by competition authorities throughout the EU. The European Commission (Commission) and the National Competition Authorities (NCAs) have investigated agreements and conduct that in their view restrict market entry of new or generic drugs.

The recent report by the Commission to the Council and the European Parliament on *Competition Enforcement in the Pharmaceutical Sector (2009–2017)* suggests that pharma cases are likely to continue to be of interest to competition authorities. Particularly high price strategies and discount regimes are key areas of likely regulatory interest at EU and national level.

In both of these areas, the antitrust issue arises out of the unilateral conduct of the company. It does not require an agreement or understanding with a competitor. However, it does require potential dominance, i.e. market power. In the absence of market power, companies are free to determine their own prices, discount schemes and pricing strategies. Where companies are dominant, they are subject to some limitations on their pricing conduct, particularly with their discount regimes but also when they increase prices.

This paper provides an overview of the current state of play of the various cases. Many of these are still ongoing or under appeal which means that the landscape will continue to develop as these cases progress.

## Excessive Pricing

There are a number of pharma cases in which significant price increases in off-patent medicines have led to investigations and fines. The UK authority, the Competition and Markets Authority (CMA), investigated Pfizer and Flynn in 2013 in respect of significant price increases to phenytoin and is currently investigating Concordia regarding the pricing of liothyronine[1] and Actavis[2] in respect of its hydrocortisone tablets.[3] The Italian Competition authority investigated Aspen in respect of cancer drugs – which in turn sparked a still ongoing EU investigation for the same drugs in other countries. Finally, the Danish Competition Council investigated CD Pharma for excessively pricing syntocinon.

A common theme in all those cases were (i) the medicines were off-patent, and (ii) the price rises were by multiples of the then prevailing price: phenytoin – eight to 25 times; liothyronine 60 times; hydrocortisone tablets 95–125 times; in CD Pharma some 20 times; and in Aspen around three to 15 times.

***Where are we now?*** Most of these cases are under appeal (Pfizer/Flynn before the UK Court of Appeal) or ongoing (Concordia, Actavis and the EU investigation of Aspen). Only CD Pharma and the Italian Aspen cases have been confirmed on appeal. Pfizer and Flynn's successful appeal before the first Competition Appeal Tribunal (CAT) provides helpful pointers on the likely UK approach pending a further judgment from the Court of Appeal which we do not expect until the end of this year at the very earliest, more likely in the course of 2020.

***Case note on Pfizer/Flynn***. The legal test for excessive pricing is set out in the United Brands judgment from the late 1970s.[4] In that case, the European Court of Justice (ECJ) set out a two-pronged test to determine whether prices are abusive: (i) first, a competition authority must show that prices are "excessive" on the basis of the difference between the costs incurred by a dominant firm and the price actually charged; and (ii) second, it must demonstrate that the excessive price is "unfair in itself or when compared to competing products".

Applying the *United Brands* methodology, the CMA found that the increases in the price charged (between eight to 25 times, depending on the distribution level and time) were both excessive and unfair in themselves, despite the fact that the resale price was ultimately some 25% lower than the price of other anti-epilepsy drugs, notably phenytoin tablets (which for specific reasons constituted a separate market).

In reaching its conclusion, the CMA adopted a "Cost Plus" approach, which allowed the two companies a specified return on sales (ROS) taking into account their direct costs and a proportion of their indirect costs, and considered that a ROS of no more than 6% would be reasonable, based on the economic value of the capsules and the fact that there were no non-cost factors which increased their value above that level. Given that Pfizer's and Flynn's prices were well above the 6% ROS level, the CMA concluded that these were unfair in themselves and that it was not necessary to reach a conclusion on whether those prices were unfair when compared to competing products (such as phenytoin tablets).

On appeal, the CAT partially quashed the CMA's decision, considering that the latter had incorrectly applied the legal test laid down in *United Brands* and set out a comprehensive checklist for the CMA to assess whether prices are excessive for the purpose of Article 102.[5] In particular, the CAT decided that:

- To determine whether prices were excessive, the CMA was wrong in relying solely on a "Cost Plus" approach and should have evaluated other available methodologies to establish a benchmark price or range.
- After selecting a benchmark price, the CMA should have compared this with the price that had been charged in practice, and determined whether the latter was excessive, taking into account, among others, the size and stability of that differential, the reasons for such differential, including the existence of regulations and barriers to entry, and wider market conditions, including the evolution of pricing over time.

- Where the excessive prong of the test is met on the basis of the above criteria, an authority should then proceed to consider whether a price is unfair. Although the *United Brands* test provides for two alternatives (price is unfair in itself OR in comparison with other products) and an authority does not need to succeed under both, due consideration must be given to any *prima facie* valid argument that a price is fair under one alternative, before finding an infringement solely on the basis of the other one. On this basis, the CMA was wrong in concluding that the price of phenytoin capsules was unfair in itself without giving proper consideration to the arguments raised by Pfizer and Flynn concerning the price of comparable products, notable phenytoin tablets.
- The CAT also considered that, even where the unfairness prong of the test is met, an authority should separately assess whether the price bears a reasonable relation to the economic value of the product. This includes looking at non-cost factors such as patient benefits and the nature of the product. In this respect, the CMA should have taken into account demand-side considerations, and particularly the therapeutic benefits for customers from using the product.

***What does it mean going forward?*** Excessive pricing cases have been rare and competition authorities do not see themselves as price regulators. Yet, there is a growing trend of excessive pricing cases particularly in the pharma sector.

Based on the pattern emerging from the cases above, companies can expect significant regulatory attention where the following two elements occur. First, there is a significant price rise typically in off-patent drugs, and typically by multiples, that is not driven by changes in the cost structure. Second, additional factors are present, such as threats of a refusal to supply or de-listing of a product, or a restructuring of the distribution of a product that deliberately or incidentally avoids other price regulation (as used to be the case in the UK).

## Discounts and Rebates

Discounts and rebates, like high prices, only give rise to potential antitrust issues when the company in question potentially holds a dominant position in respect of all or some of the products in the discount scheme.

***Background***. Although not specific to the pharmaceutical sector, the most recent landmark case concerning discount and rebate schemes is the European General Court's judgment of 2017 in *Intel*.[6]

Following that judgment, we can distinguish between two broad categories: (i) quantity discounts/rebates (i.e. solely linked to volume purchased) – these are generally not considered anti-competitive if they reflect gains in efficiency/economies of scales and such savings are passed on to customers; and (ii) all other loyalty inducing discounts/rebates which can be anticompetitive if they have the potential of excluding competitors that are at least as efficient as the dominant undertaking, taking into account all relevant market circumstances. If they do not have that potential, they do not give rise to an antitrust problem.

Discounts and rebates that are tied to exclusivity or near exclusivity, are formally still subject to an infringement presumption. However, if the parties can provide evidence that they do not foreclose access of competitors that are as efficient, then, the presumption disappears and the authority needs to demonstrate foreclosure effects.

Each discount regime is different and product and market specific, so general guidance will always be imprecise.

Areas that are most likely to attract regulatory attention are those discounts that are (i) retroactive, i.e. those applicable to the total number of units purchased once a certain volume is reached, rather than the units above the threshold, (ii) individualised for each customer or (iii) targeted at particular competitor activities, and (iv) have large discount steps from one level to another.

***Case update on Remicade***. On March 2019, the UK's CMA issued a case closure decision finding no grounds for action in its almost four-year investigation into the discount regime of Merck Sharp & Dohme's (MSD) infliximab product *Remicade*.

The CMA investigated a discount regime that in its view was specifically designed to prevent or severely restrict the entry of a biosimilar product. The aspects highlighted in its decision were the following: (i) the scheme was individualised and tailored on a region/sub-region basis according to purchasers' individual expected demand; (ii) MSD's discount scheme was designed so that a single price would apply to all units purchased during the contract period and depending on total purchases; (iii) the proportion of total demand that a region/sub-region had to purchase to obtain the first level of discount corresponded to a very large proportion of the total expected demand for *Remicade* (85%); and (iv) over the portion of the market where MSD was likely to face competition (i.e. the "contestable" demand), the NHS would be dis-incentivised to switch to competing biosimilar products and biosimilar suppliers would have to charge very low prices in order to match the effective price charged by MSD.

Even though the decision ultimately exonerates the company, the CMA strongly asserted that it did not have a legal obligation to base its findings on the As-Efficient Competitor (AEC) test and did not apply this to reach its conclusions. The CMA specifically rejected submissions on the AEC test as not being the only way in which a discount may be assessed. In particular, the CMA considered that the AEC test may set too high a threshold for finding a discount to be an abuse, which may lead to the risk of under-enforcement.

Despite the above, the CMA concluded that contrary to the company's and the NHS's expectation, assumptions around the degree of clinical caution towards competing biosimilars and the strength of the financial incentive created by the discount scheme proved incorrect. This meant that there was no foreclosure, and hence, there was no competition law breach.

This decision does not rest easily with the trend at EU level culminating in the *Intel* judgment. Nor does it sit easily with the CMA's June 2015 guidance on the application of competition law to discounts/rebates schemes. There, consistent with the *Intel* decision, the CMA endorsed the relevance of the AEC test by affirming that a discount or rebate may raise concerns if it forces a supplier competing for the contestable portion of demand to price below the dominant company's costs.[7] Given that ultimately this is a clearance decision, these points will not be tested on appeal.

***What does it mean going forward?*** The UK cases (both *Remicade* and the earlier case leading to the CMA's 2015 guidance) demonstrate that discount cases are not straightforward and that they are heavily fact-specific. Even though the *Remicade* decision ultimately exonerates the company on the facts in question, it seems reasonably clear that under a not very different set of facts the CMA would have proceeded with an infringement finding.

The largest part of the decision discusses – for the CMA – the problematic aspects and provides a clear indication on how the CMA will pursue future discount cases.

Discount schemes with the following hallmarks are in our view most likely to attract regulatory attention. First, where the discount is individualised rather than standardised across the generality of potential beneficiaries. Second, where the size of the incontestable share of demand is large compared to the contestable share. Third, where the scheme introduces some form of exclusivity or near

exclusivity to the benefit of the dominant undertaking. Fourth, where internal documentation shows an intention to foreclose competitors.

Finally, it is important to note that even if an investigation is successfully defended (as in *Remicade*) this will have involved significant amounts of resources and business disruption. The *Remicade* decision came at the end of an almost four-year investigation, a formal statement of objections, written response and hearings.

## Endnotes

1. CMA press release of 21 November 2017.
2. CMA press release of 16 December 2016 and 3 March 2017.
3. A number of other ongoing investigations are pending with the CMA, although it is unclear whether these relate to excessive pricing allegations.
4. Judgment in case C-27/76.
5. CAT judgment in cases 1275-1276/1/12/17.
6. Judgment in case C-413/14 P.
7. The CMA referred, in particular, to the long run average incremental cost of production.

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Mr. Schmidt has extensive experience advising pharmaceutical and medical device companies on pricing matters, including a number of dawn raids and ensuing investigations in reverse payment patent settlement cases both at the EU and UK level (*perindopril*, *modafinil* and *paroxetine*). Mr. Schmidt has represented a company in the UK *phenytoin* excessive pricing investigation and most recently a pharma company in one of a number of investigations started in November 2017 which was closed without an infringement finding at the end of 2018.

He also advises on parallel trade and supply chain design as well as pricing and discount regimes.

Mr. Schmidt has in-depth experience representing clients on complex competition litigation, such as successfully obtaining an interim injunction against Barclays bank for a refusal to supply a business (a case which subsequently settled). He has also acted in follow-on damages actions before the Competition Appeal Tribunal.

Mr. Schmidt has been consistently ranked as a leading lawyer by *Chambers UK* ("*very knowledgeable, easy to work with and adept at explaining complicated issues*"), *Chambers Europe*, and *Chambers Global*, as well as *The Legal 500*.

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Arnold & Porter

Arnold & Porter is an international law firm with nearly 1,000 lawyers in 15 offices in the USA, together with offices in Belgium, China, South Korea, Germany, and the UK.

The EU life sciences team, headed by Ian Dodds-Smith and based in London, has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the life sciences sector.

The team of lawyers specialising in this field in London is complemented by Arnold & Porter's highly regarded pharmaceutical and medical devices regulatory practice headed by Dan Kracov in Washington, D.C., giving a combined team of over 40 lawyers.

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Chapter 2

# Australia


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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

In Australia, the advertising of medicinal products is governed by the Therapeutic Goods Act 1989 (Cth) ("the TG Act") and its subordinate legislation (principally, the Therapeutic Goods Regulations 1990 (Cth) ("the TG Regulations")). The TG Act is administered by the Therapeutic Goods Administration ("the TGA"). "Therapeutic goods" is the phrase used in Australia to describe medicines and medical devices.

The advertising of therapeutic goods is also subject to the same laws which regulate advertising generally, most notably, the Competition and Consumer Act 2010 (Cth) ("the CC Act"), and the Australian Consumer Law ("ACL"), which is Schedule 2 to the CC Act. The CC Act is administered by the Australian Competition and Consumer Commission ("the ACCC").

There are also a number of Codes of Practice which contain provisions relating to the advertising of therapeutic goods. The most relevant to the advertising of medicinal products are:

- the Therapeutic Goods Advertising Code (No 2) 2018 ("the TGAC") which applies to all advertisements for therapeutic goods other than those directed at healthcare professionals or wholesalers of therapeutic goods. The TGAC is delegated legislation, made under the TG Act;
- the Medicines Australia Code of Conduct ("MACC") and supporting Guidelines, which relate to the promotion of prescription-only medicines. Edition 18 of this Code commenced on 16 May 2015 together with an updated version of the Guidelines. Most innovator companies in Australia are members of Medicines Australia, and are subject to the MACC as a condition of their membership. Furthermore, the listing of prescription medicines by the TGA is generally subject to a condition that promotional material for the medicine must comply with the MACC;
- the Generic and Biosimilar Medicines Association ("GBMA") Code of Practice, the fourth edition of which came into effect in December 2015;
- the Australian Self-Medication Industry ("ASMI") Code of Practice, which relates to the advertising of non-prescription consumer healthcare products. The ASMI Code of Practice was last revised in January 2015;
- the Medical Technology Industry Code of Practice ("MTIC") (administered by the Medical Technology Association of Australia ("MTAA")), 10th edition, effective from December 2018, which relates to the behaviour of medical device and technology companies; and
- Pathology Technology, Australia's Industry Code of Conduct applies to the behaviour of companies who market *in vitro* diagnostic products in Australia. The third edition of the Code of Conduct was published in September 2018.

### 1.2 How is "advertising" defined?

The TG Act defines "advertise" as follows:

> "*in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:*
>
> *(a) is on the label of the goods;*
>
> *(b) is on the package in which the goods are contained; or*
>
> *(c) is on any material included with the package in which the goods are contained*."

Under this definition, whether or not something is an advertisement depends on whether it is "intended" to promote the use or supply of goods. We are not aware of any case law that determines how this test of intention is to be applied, but in practice it is applied broadly.

The question of whether a particular statement constitutes an advertisement is also commonly tested under the industry codes. For example, the MACC defines "advertisement" in very similar terms to "advertisement" under the TG Act.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Advertisements for prescription medicines, which can only be directed to healthcare professionals, are regulated by the MACC. Sales representatives and those directly involved in the development, review and approval of promotional materials relating to prescription medicines are required to complete a training course in relation to the MACC and trade practices and privacy laws, to the extent that it is relevant to their role within a specified time of commencing employment, and on an ongoing basis, as needed.

There are otherwise no formal requirements for the types of internal approval process which companies must have in place (although there are certain types of advertisements which must be approved by appropriate regulatory authorities (see the answer to question 1.5)). It is rather a matter of risk management.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

There are no legal or code requirements for companies to have specific standard operating procedures ("SOPs") in relation to advertising or to employ personnel with a specific role in relation to advertising. The advertising activities of companies are strictly controlled and directed by the TG Act, TG Regulations and TGAC, along with the MACC and other industry codes.

However, some codes, most particularly the MACC (which applies to prescription medicines), have specific requirements for policies or guidelines for some promotional activities. For example, clause 9.7.2 of the MACC requires companies to develop clear guidelines for the provision of sponsorships to healthcare professionals, which must be publicly disclosed if required (see question 5.2 below).

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

There are certain types of advertisement which must be approved before they can be used. Generally, an advertisement must be approved if:

- it relates to a non-prescription medicinal product;
- its intended audience is broader than healthcare professionals (including alternative health practitioners) or wholesalers of therapeutic goods;
- it contains more information than the name of the goods, the price of the goods, a picture of the goods and the name of a supplier; and
- it is intended for publication in newspapers or magazines, in the form of posters/billboards in public places, or broadcast on radio, television or film.

The power to approve advertisements is delegated to one of the industry peak bodies. Depending upon the nature of the medicinal product, or the type of advertisement, applications for approval are made to ASMI or Consumer Medicines Association.

The approvers are allowed 60 days to approve advertisements, but usually try to complete their review within 10 days.

There is a fee for approval.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The answer to this question depends on the nature of the advertisement.

In the case of advertisements which require approval, the TGA has the power to withdraw the approval of any advertisement, in effect stopping its further publication. In the case of advertisements to the general public which do not require approval, the TGA has a wide range of powers, which include:

- the power to issue a notice prohibiting a person from publishing a particular advertisement, if the TGA forms the view that the advertisement contains a representation which is false or misleading;
- the power to issue a substantiation notice to a person apparently responsible for advertising therapeutic goods requires that person to provide information to substantiate claims made in the advertisement and, finally, may issue a public warning notice;
- the power to require a person who advertises in breach of the relevant legislation to cease the advertisement, make a retraction or correction, recover and destroy copies of the advertisement or cease making a particular claim or representation; and
- in certain cases, the power to issue a public warning notice in respect of an advertisement.

The TGA does not have any specific powers in relation to advertisements for prescription products (which can only be directed at healthcare professionals). However, Medicines Australia, which hears complaints about such advertisements, is entitled by the MACC to order their withdrawal, and to order corrective advertising.

There is a right to an internal merits review of some, but not all, of the TGA's powers outlined above. If a company is not satisfied by the internal merits review, then it may seek a further merits review from the Administrative Appeals Tribunal (a tribunal which conducts merits reviews of administrative decisions).

In addition to the powers which are directed specifically at therapeutic goods, the ACL empowers the ACCC to seek court orders for the withdrawal of advertisements, and for retractions or corrective advertising. It is possible that the ACCC would exercise its powers in relation to a therapeutic good in an appropriate case. Similar actions may also be brought by private citizens and competitors.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

There are a number of ways in which an advertiser might be subject to sanction.

(a) Criminal Offences

First, the TG Act and TG Regulations create a number of offences relating to advertising. These include both criminal offences and civil penalty provisions. The penalties imposed for a breach of these rules are fines of up to AU$10,500,000 for corporations and AU$1,050,000 for individuals.

The TGA is responsible for enforcing these provisions.

(b) Industry Bodies

Each of the codes mentioned above include a complaints resolution body.

The most commonly used is the Medicines Australia Code of Conduct Committee, which hears complaints relating to prescription-only medicines. The Committee can impose sanctions on Medicines Australia members, including fines of up to AU$300,000, corrective advertising and the suspension or expulsion of members.

(c) General Law

The ACL contains a number of provisions which impact on advertising, including the advertising of medicinal products. The most important is section 18 of the ACL, which prohibits a corporation from engaging in "misleading or deceptive conduct" in the course of "trade or commerce". This provision has been widely used to challenge advertisements and promotional conduct.

(d) Practical Considerations

Generally speaking, it is the less formal measures which ensure compliance with the rules in relation to the advertising of medicinal products.

Prosecutions or civil penalty proceedings for breaches of the TG Act are extremely rare, although this is likely to change as a result of the recent reforms to the regulation of advertising, including the abolition of the Complaints Resolution Panel.

Medicines Australia publishes regular quarterly reports of complaints considered by its Code of Conduct Committee. During the 12 months from 1 July 2017 to 30 June 2018 there were six new complaints received by the Code of Conduct Committee (three of which were against non-Member companies who declined to participate in the Medicines Australia complaints resolution process). These include complaints initiated by competitors and by healthcare professionals. There were no complaints initiated by members of the general public, although such complaints are permitted under the MACC.

Competitor-initiated court action in respect of advertisements is rare, although it does occur. A recent example is *Novartis Pharmaceuticals Australia v Bayer Australia* (2015) 22 ALR 621 which concerned an unsuccessful claim by Novartis that Bayer's marketing of Eylea was misleading.

Furthermore, Reckitt Benckiser was subject to an AU$6 million civil penalty in respect of the promotion of Nurofen (ibuprofen). The proceedings were brought by the ACCC in respect of the promotion of different products to treat specific types of pain in circumstances where the formulation of each product was the same *ACCC v Reckitt Benckiser* (2016) 340 ALR 25.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

Complaints relating to promotional material for prescription medicines are directed to Medicines Australia. If such complaints are directed to the TGA, it will forward these complaints to Medicines Australia.

Section 25 of the MACC deals with complaints against non-members. Complaints concerning the conduct of non-members will be forwarded to the non-member with an invitation to have the complaint adjudicated by the Code Committee in accordance with Section 20 of the MACC and to abide by the Code Committee's decision and any sanctions imposed. If the non-member declines the invitation, Medicines Australia has the right, but not the obligation, to forward the complaint to the TGA or the ACCC.

Complaints relating to the promotion of medical devices and non-prescription medicines to the general public are handled by the TGA.

Generally speaking, the TGA allows complaints to be addressed through whichever one of these is the most appropriate mechanism.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The chief recourse for Australian companies who believe that their competitors are using advertising to gain an unfair competitive advantage, is section 18 of the ACL.

There are relatively few restrictions on persons who may take action under section 18; it may be used, for example, by public interest groups. The ACCC may also commence proceedings for breach of section 18, in which case, the court may impose fines for its breach.

It is also reasonably common for companies to make complaints to either the TGA or Medicines Australia about allegedly misleading or unfair advertisements.

The MACC provides that its complaints resolution procedure should not be used by pharmaceutical companies simply as a competitive tool (see Appendix 1 to the MACC). Nevertheless, competitors often bring complaints under the MACC on the basis of public interest in healthcare professionals receiving balanced, accurate and correct information about prescription products.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Until a product is authorised (or, to use the Australian terminology, registered, listed or included on the Australian Register of Therapeutic Goods ("the ARTG")), there is a blanket prohibition on the publication of any advertisement for therapeutic goods. There is also a blanket prohibition on making claims that a person can arrange the supply of unregistered therapeutic goods.

However, not all references to a product will necessarily be "advertisements" (see the discussion of the definition of "advertisement" under question 1.2 above).

Both the TG Act and the MACC treat each indication of a product as a separate product, so the prohibition on advertising unregistered products also applies to promoting registered products for uses outside of their approved indications.

The MACC contains provisions which set out what manufacturers and suppliers are allowed to say about unregistered prescription products (section 1.4 of the MACC). Company personnel from the medical department, including field-based medical personnel, may provide information to healthcare professionals on unapproved products or subjects not covered by the Product Information (e.g. unapproved indication) upon receipt of an unsolicited request. Such information must be compiled and provided by medical department personnel and not sales team members.

The MACC allows companies to provide published literature, sponsor scientific meetings and supply or display educational material at meetings.

It also permits companies to provide information at international or Australasian congresses if a product or indication is approved or registered in a country from which a significant number of attendees originate, even if the indication is not approved in Australia. In this instance, educational and promotional material, along with Product Information, may be made available, provided it complies with section 9.6 (Trade Displays) of the MACC and is clearly identified as not being approved for that indication in Australia. Starter packs

of products or information about an unapproved indication may be displayed, but not distributed.

Finally, it permits companies to make information about non-approved indications for a product available on Medical Information websites or applications, subject to certain limitations (including the fact that the website is password protected so as to only allow access by healthcare professionals).

In general, there are no specific prohibitions on persons other than manufacturers or suppliers making statements about unregistered products or indications, provided that those statements do not amount to "advertisements" – that is to say statements intended to promote the use or supply of the goods – and make it clear that the statement relates to unregistered products or indications.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

The publication of information about unauthorised medicines that amounts to an advertisement or promotion of the medicine in question including off-label information is prohibited. As noted above, this raises the question of whether there is an intention to promote the use or supply of the product. Educational information including medical literature may be permitted to be provided on request.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

There are no provisions in the TG Act which deal specifically with press releases.

However, the MACC does deal with press releases about prescription-only medicines. It says (section 13.4.1):

> "*Media releases must be educational and not include promotional statements or claims, or comparisons with other products. A product specific media release must be in language that reflects current community standards*."

Companies should not issue product-specific media releases to announce a new product, or major indication to the general public, until the product has been registered in Australia and reasonable steps have been taken to inform the medical and pharmacy professions of its availability.

These provisions do not prohibit a company listed on the Australian Securities Exchange from issuing a non-promotional product-specific media release in line with its continuous disclosure requirements.

No other product-specific media releases are permitted by the MACC. In addition, a company may respond to media enquiries, comment to the journalist or editor on published articles containing incorrect information and respond to inquiries from members of the general public in an educative and non-promotional manner.

Product-specific media releases about unapproved products or indications directed at health professionals are otherwise subject to section 1.4 of the MACC which prohibits the consolidated provision of information about unapproved products and indications to healthcare professionals.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Yes, but only in response to a specific request from the healthcare professional. Generally, it is acceptable to send healthcare professionals published, peer-reviewed articles or proceedings of scientific symposia, but not company-authored material which falls outside of this description. Information provided must be balanced and not promotional and should be distributed by a company's medical department.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The ECJ judgment in the *Ludwigs* case answered a question which is related to the interaction between German national law and the EC Directive 2001/83. It is not part of Australian law.

Questions 2.1 to 2.4 describe the circumstances in which details about unapproved medicinal products may be made available to healthcare professionals or the general public.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

There are no specific provisions or guidelines dealing with the provision of information about unregistered products or indications in this context.

However, such information may constitute an advertisement, as that term is defined in the TG Act and, as a result, would (technically at least) breach the TG Act. That being said, providing it was clear that there was no intention to sell the product in question until it was approved, such conduct would be unlikely to attract censure or sanction.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The TG Act prohibits the promotion of any therapeutic good that has not received regulatory approval. The MACC provides (in sections 12.1 and 13.11) that the sole purpose of market research activities must be to collect data, and not as a means to promote to or reward healthcare professionals or the general public. Section 12.1 specifically provides that market research may be undertaken in respect of an unapproved indication, but must not be used as a means to promote an unapproved product or indication. There must be a genuine initiative to collect relevant and useful information to enhance the quality use of medicines. Market research studies must be clearly identified as such, when an initial approach is made to healthcare professionals.

The Australian Market and Social Research Society's Code of Professional Behaviour provides guidance to researchers in the practice of market research.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

It depends upon the type of advertisement, the type of product and the length of time the product has been on the market. By way of example, for advertisements for prescription-only medicines published in periodicals, the MACC provides that the advertisement ("primary advertisement") for a product (or indication) which has been on the market for less than two years must contain:

- the product's brand name;
- the Australian-approved names of its active ingredients;
- the name of the supplier and its location;
- a form of product information (a statement in a specified form setting out information such as the approved indications, contraindications, clinically significant warnings, precautions for use and adverse events and interactions);
- all PBS listings, including any restrictions (the PBS, or Pharmaceutical Benefits Scheme, is the government scheme whereby the supply of many prescription-only medicines is subsidised by the Federal government); and
- a clear and unambiguous statement that prescribers should review the full product information before prescribing.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

The precise requirements will vary from product to product. However, in the case of prescription medicines, the MACC contains detailed provisions explaining what information must be contained in an advertisement. Those requirements include a range of specific positive obligations, as well as some general prohibitions (for example, they must be "current, accurate, balanced and must not mislead either directly, by implication, or by omission", MACC, section 1.3).

In Australia, the document equivalent to the SmPC is the Product Information ("PI"). There is no prohibition on advertisements including references to studies which are not in the PI, although if such studies relate to indications which are not approved in Australia, that will give rise to a separate difficulty. However, the MACC requires that some kinds of advertisement (called Primary Advertisements) contain either the PI or an abridged version of the PI. It also requires that all written advertisements for a product be Primary Advertisements for 24 months after the first advertising of a new product or indication or 12 months after a change of clinical significance to the PI.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The MACC requires companies to obtain a healthcare professional's documented consent to include their name or photograph in any kind of promotional material. Whenever a healthcare professional's name is specified in any kind of promotional material, other than in citations of published references, the company should ensure the healthcare professional is aware of and provides documented approval for the use of his or her name in the context of the entire promotional material.

The MTIC also provides that the name or photograph of a healthcare professional must not be used without the written permission of the professional, and must not be contrary to the ethical guidelines of the professional association of the professional, or be likely to mislead, deceive or confuse.

Advertisements subject to the TGAC (that is, advertisements directed at the general public) must not contain or imply endorsement by individuals who are healthcare professionals by way of their representation in advertisements or academic qualifications, or who are likely to be known as healthcare professionals by the reasonable person.

Many healthcare professionals are also subject to ethical requirements and codes of practice which provide guidance on suitable involvement with industry. Companies should be aware of those obligations when approaching HCPs.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There is no specific requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims are made.

The MACC provides that any comparison must reflect the body of evidence and does not mislead by distortion, by undue influence or in some other way. Comparisons must be factual, fair, capable of substantiation, and referenced to its source, and must not be disparaging.

According to the provisions of the MACC, the accepted level of statistical significance is $p < 0.05$. If comparative data that are not statistically significant are used:

- the lack of significance must be stated explicitly; and
- the data must not be used to generalise or to indicate superiority or inferiority.

If there is no statement of the significance or lack of significance of particular comparative data, the lack of a p value must be explicitly stated.

An advertisement using such comparative data must also distinguish between mathematically determined statistical significance as compared with clinical significance.

The Guidelines to the MACC ("the Guidelines") state clearly that, "unequivocal supporting evidence", is required for comparative claims.

Therefore, considerable care must be taken in making comparative claims based on data from different studies. There have been several instances where such claims have been challenged on the basis that the studies are too different to permit an accurate comparison of the relevant data.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

There is no statutory prohibition on the use of comparative advertisements, or the mention of competitor products in such advertisements.

However, there have been many instances where the courts have held that comparative advertising has been misleading or deceptive. This means that special care must be taken in its use.

The MACC has a provision which deals specifically with comparative advertising (section 1.8). It provides:

> "*The intention of this provision is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.*
>
> *Care must be taken to ensure that any comparison properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. Comparisons of products must be factual, fair, capable of substantiation, referenced to its source; and must not be disparaging. 'Hanging' comparatives – those that merely claim that a product is better, stronger or more widely prescribed, etc., must not be used.*
>
> *Claims of comparative efficacy or safety must not be based solely on a comparison of Product Information documents that does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Australian as well as overseas Product Information documents. These claims must be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter*…"

Section 1.8 also governs the use of comparative studies; see question 3.4 above.

There is no prohibition on making references to a competitor's product which has not yet been authorised in Australia in comparator advertisements. However, in making such claims, it is important to bear in mind the general prohibition against advertising for unapproved indications in Australia, and the prohibitions against misleading or deceptive conduct.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Companies may supply to healthcare professionals, on request, literature about subjects not included in the Product Information for a particular prescription product, including unapproved indications (section 4.2.4 of the MACC).

The MACC provides that the general interpretation and conclusions of any reprints of journal articles, proceedings of educational events or summaries of literature used in promotion must be consistent with the product information for both the sponsor's products, and any competitor's products with which a comparison is being made.

Quotations relating to prescription products, taken from public broadcasts or private occasions, including medical conferences or symposia, should not be published without the speaker's consent. In addition, if a company sponsors the reporting of a congress or symposium, this activity must comply with the MACC.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There are no statutory provisions which deal specifically with the use of "teaser" advertisements.

The MACC contains provisions which regulate, with great particularity, the form of advertisements for prescription-only medicines to healthcare professionals. For example, most advertisements must contain some form of product information. Subject to content and context, it is possible that a teaser advertisement would not comply with these requirements, and would therefore breach the MACC.

Nevertheless, there have been instances of teaser (or "disease state") advertisements directed at the general public which have survived regulatory scrutiny. These are now specifically regulated by section 13.8 of the MACC.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

To the best of our knowledge, this problem has not previously arisen in Australia. However, reading the MACC and the TG Act strictly, the promotion of Product B for the use in question would be a breach of both and that a variation of the Product Information for Product B would be required before any advertising could be undertaken which referred to the use of Product B for the indication in question.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes. If the product is a prescription-only medicine then the MACC provides that distribution of samples (called "starter packs" in the MACC) must be carried out in a reasonable manner including compliance with the conditions of registration of a product on the ARTG.

The MACC provides that starter packs should only be supplied for one of four purposes:

- for immediate use in the surgery for relief of symptoms;
- for the use of alternative treatments, prior to a prescription being written;
- for after-hours use; or
- for gaining familiarisation with the product.

The MACC also contains specific rules regarding the size and quantity of samples which can be supplied, and the requirements to keep adequate records.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

The MACC prohibits the giving or offering of gifts, benefits in kind and pecuniary advantages to healthcare professionals or administrative staff as an inducement to recommend, prescribe, dispense or administer

a company's product(s). It also prohibits the provision of gifts or offers to healthcare professionals, subject only to certain specific exceptions, namely:

- company-branded pens and notepads provided at company-run or sponsored education events;
- medical educational material, including literature reprints;
- sponsorship to attend educational events. There are limitations on the extent of such sponsorship, which are discussed further in section 5 below; and
- hospitality at an educational event, which must be secondary to educational content. Again, the specific limits on hospitality are discussed in section 5 below.

Under the MTIC, a medical device company must ensure that sales of medical technology are made solely on the basis of efficacy, safety, quality, price and service and never on the basis of a healthcare professional receiving payments, gifts or hospitality.

Thus, a medical device company may provide a healthcare professional with an item that benefits patients or serves a genuine educational function provided that the item has a fair market value of less than AU$100, except in the case of medical textbooks or anatomical models. The MTIC does recognise that there is, within the medical technology industry, a legitimate practice of providing to healthcare professionals appropriate sample medical technologies for genuine training, education or medical technology evaluation purposes. However, no non-educational branded promotional item may be given to a healthcare professional, even if the item is of minimal value and is related to the healthcare professional's work or for the benefit of patients.

Under the MTIC, a medical device company may provide hospitality to healthcare professionals. The specific limits in relation to hospitality are discussed in section 5 below.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

There are no rules which prevent manufacturers or suppliers from giving gifts or donations to healthcare institutions or to donate equipment or fund the cost of certain types of services. Both the industry codes and also anti-bribery legislation in Australia provide important prohibitions against the giving of personal gifts.

The MACC contains general provisions which impose obligations on promoters of prescription-only medicines in their dealings with potential customers. For example, the sponsorship of any healthcare professional activity must be able to successfully withstand professional and public scrutiny, conform to professional and community standards of good taste and enhance the quality use of medicines.

The MACC also prohibits any sponsorship from being conditional upon an obligation to prescribe a particular product or to have any conditions which might interfere with a healthcare professional's prescribing or dispensing practices. It requires companies to develop clear guidelines for awarding sponsorship.

There are similar, although less detailed, provisions in the MTIC.

If a gift or donation is too closely aligned to a promotion or advertisement, it might breach some other rule or provision of the codes.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Involvement in educational goods and services is prescribed in sections 4 and 9 of the MACC. Most importantly, section 4.1 of the MACC specifies that all items of an educational nature, whether for the education of healthcare professionals or to be used by a healthcare professional in consultation with a patient, must be dedicated to improving the quality use of medicines or assisting a patient in their understanding of a condition or disease. Materials supplied for medical education must include the name of the supplier and city, town or locality of the registered office. Materials supplied for medical education may include promotional claims or statements, but must comply with sections 1, 2 and 3 of the MACC. Such accompanying material should be clearly identified as promotional material.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Other than the general provisions set out above, there are no specific provisions which prohibit the provision of volume-related discounts.

However, it would be necessary to ensure that any volume-related discounting arrangement does not infringe Australian competition (anti-trust) law.

In addition, while the MACC does not have anything to say about volume-related discounts expressly, it is important to ensure that a volume-related discount does not infringe the general prohibition in offering pecuniary benefits as an inducement to prescribe (see question 4.2 above). Generally speaking, an arrangement for a volume-related discount which is made with the purchasing department of a healthcare institution will not raise issues, but an arrangement which delivers benefits directly to clinicians may.

Finally, if a prescription product is listed on the PBS, certain aspects of its pricing are regulated and, depending on the particular product, this might limit the way in which volume-related discounts can be applied. The PBS scheme requires sponsors of PBS-listed products which are on the PBS's F2 formulary (the formulary for products which have one or more generic competitors) to disclose to the government the "true" price at which they sell their products, by disclosing all "benefits" which are provided to purchasers in community pharmacy or private hospital settings. Those true prices are then used to calculate a reduced subsidy which the federal government will provide for the medicine in question.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Most offers to provide or pay for additional services or equipment contingent upon the purchase of medical products would amount to

an inducement to prescribe the particular product. If so, then such an arrangement would be prohibited by relevant industry codes, including the MACC (see the discussion at question 4.3 above).

However, there are some circumstances where companies are able to offer to pay the cost of certain services associated with the use of their product, provided that there are sufficient safeguards which prevent that payment from influencing the ultimate decision about prescription. These are limited and apply only in specific circumstances. Whether an arrangement of the sort described could be safely created would depend on a more detailed analysis of the facts, in particular the relative value of the administration and training and its degree of connection to the product in question.

Assuming that such safeguards can be put in place, there is an additional restriction. The Health Insurance Act 1973 (Cth) prohibits any person from making a "contract of insurance" in respect of medical services funded by Medicare, Australia's universal healthcare system. In certain circumstances, an offer to pay for the provision of medical or technical services may breach this prohibition.

A final difficulty which may arise is whether the arrangements amounted to a misuse of market power in breach of competition law. This would, again, depend on an analysis of specific facts and, in particular, whether the company could be said to have power in the relevant market.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

There is nothing which prevents a supplier or manufacturer offering a refund scheme if a product does not work. Indeed, if a pharmaceutical product proves to be defective, then the supplier is probably obliged by law to refund the purchase price of the product.

However, if the product is a prescription-only medicine, then it may not be possible to promote such a scheme effectively. The advertising of prescription-only medicines direct to consumers is prohibited, and advertisement is defined extremely broadly. A widely publicised refund scheme might well be seen as an inducement to consumers.

Furthermore, where a supplier of goods offers a warranty or guarantee of performance to users of a product, the ACL requires that certain standard wording be included as part of the warranty or guarantee. The effect of this language is that the warranty or guarantee is in addition to, and not instead of the users rights under the ACL.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes, they can.

The MACC provides that pharmaceutical companies may sponsor "educational events" organised by a society, college, university or other healthcare professional organisation and the attendance of healthcare professionals at these events if:

- the primary objective of the meeting is to enhance medical knowledge and the quality use of medicines in Australia; and
- they conform with the rules relating to the sponsorship of healthcare professional activities (see question 4.3).

The company must ensure an appropriate balance between the duration of educational content and any hospitality provided to delegates.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

While there are laws in each state and territory of Australia which prohibit commercial bribery, there is no single anti-bribery/anti-corruption authority. Rather, such laws are investigated by state police forces (and in the case of Federal offences, the Australian Federal Police) and where necessary, referred to public prosecutors for enforcement.

In addition, some Australian states have commissions established specifically to investigate public corruption (for example, the Independent Commission Against Corruption in New South Wales). As such, there is no formal relationship between the enforcement of advertising rules and anti-bribery laws, and dual enforcement is theoretically possible. So far as we are aware, pharmaceutical companies have yet to be subject to investigation for breaches of anti-bribery laws in Australia.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The industry codes contain rules governing the offering of hospitality to healthcare professionals.

The most comprehensive rules are those in the MACC relating to the offering of hospitality by persons supplying prescription-only medicines, discussed below.

Under the MACC, if an Australian healthcare professional's attendance at an overseas event is sponsored by an Australian company, or if the hospitality is provided overseas in the context of the healthcare professional providing a service to an Australian company, then the MACC requirements will apply. Accordingly, any arrangements should be subject to approval by the Australian affiliate.

The MTIC does not expressly address the question of hospitality provided overseas, but we think the same approach should comply.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The MACC permits prescription pharmaceutical companies to sponsor healthcare professionals to attend Australasian and

international educational and scientific meetings, provided the meeting is directly related to the healthcare professional's area of expertise. Companies are required to have clear guidelines about the way in which they award such sponsorship and to ensure that there is a formal agreement or an exchange letter in place which records the terms of the sponsorship.

The MACC permits a company to pay for travel to and from a meeting, provided that for an Australasian event, travel must be by economy class only, but for international events, travel may be by economy or business class. The MACC also permits a company to pay for a healthcare professional's "reasonable" accommodation expenses, including an allowance for meals and beverages (provided that such allowance is not "excessive").

The MACC prohibits companies from paying for, or subsidising, the travel costs of a healthcare professional's guest, family or companion. It also prohibits delegates being paid for their time to attend a company educational event or international educational events.

The MACC also prohibits companies from providing "entertainment" for healthcare professionals.

Where a company provides hospitality in connection with a medical educational event it runs or sponsors a healthcare professional to attend, the MACC provides that within Australia the maximum cost of "a meal" including all food and beverages, but not including taxes and gratuities, must not exceed AU$120. The MACC also says that the maximum amount would only be appropriate in exceptional circumstances. Overseas the Australian maximum, or local guidelines, are to be used as a guide.

The MTIC permits medical device companies to sponsor the attendance of healthcare professionals at conferences primarily dedicated to promoting objective medical, scientific and educational activities and discourse, but requires that the conference organiser choose the recipient of the sponsorship and make all of the travel and accommodation arrangements. The payment in respect of the sponsorship must be made to the conference organiser.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Relationships with healthcare professionals, including involvement in educational meetings, are regulated by section 9 of the MACC. Section 9.5.5 specifies that any hospitality provided at a sponsored educational event must be secondary to the educational purpose. Sections 9.4.5 and 9.7.6 specify that for educational meetings directly organised by companies, and that are the responsibility of companies, all accommodation must be of a reasonable level and be appropriate for the time and duration of the meeting and origin of the delegates. Meals provided at an educational meeting should be secondary to the educational content of the meeting and must not be excessive (stated in sections 9.4.3 and 9.7.7). No entertainment should be provided (sections 9.4.6 and 9.7.10).

Furthermore, as specified in sections 9.4.2 and 9.5.4, the venue and location must be conducive to education and learning and must not be chosen for its leisure, sporting or recreational facilities. A company must not subsidise or pay for the costs of family or companions of attendees at educational meetings.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes. There is nothing which prohibits suppliers and manufacturers of medicinal products from retaining healthcare professionals for the purposes of providing expert services. It is common practice for Australian companies to retain panels of independent experts with whom they consult in relation to their products.

Section 9.9 of the MACC deals specifically with advisory boards and requires the need for the advisory board to be documented and genuine. It also requires that board meetings be held in Australia (except where being held in conjunction with an international symposium or an international advisory board meeting) and that records of service and minutes of meetings be kept by the company.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes, the MACC permits healthcare professionals to be paid for taking part in post-marketing surveillance studies, provided that the payment is commensurate with the work involved and is not based on the number of prescriptions written. The rules governing post-marketing surveillance studies are contained in section 10 of the MACC.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes, it is possible to pay healthcare professionals to take part in market research provided that the sole purpose of the market research is to collect data and not a means to promote or reward healthcare professionals.

The MACC provides that any payment to healthcare professionals "must be kept to a minimum and should not exceed a level commensurate with the time involved" (section 12.3). If a voucher is given instead of cash payment, it must be valid only to obtain an item directly relevant to the practice of medicine or pharmacy. A voucher for entertainment is not acceptable. A donation to a registered charity *in lieu* of cash payment may be acceptable if the value is commensurate with the work undertaken.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, it is possible.

Advertisements for medicinal products which are to be published in newspapers or magazines, or in the form of posters or billboards, or broadcast on radio, television, or film, must be approved before they are used. See question 1.5 above.

All advertisements for medicinal products directed at the general public must comply with the provisions of the TG Act and the TG Regulations and also with the TGAC, as well as with the provisions in the ACL which relate to advertising generally.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

The TG Act prohibits the advertising of prescription-only medicines to the general public.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

The construction and content of disease education campaigns are governed by section 13.8 of the MACC. The emphasis of these campaigns should be on the condition and its recognition as opposed to the treatment options. This does not prevent campaigns referring to the availability of different treatment options, so long as it is done without encouraging an individual to seek a prescription for a prescription-only product.

Disease education activities must not include any reference to a specific prescription product, or this would breach the prohibition on direct-to-consumer advertising.

Section 13.8.7 requires the name of a pharmaceutical company to be identified in any disease education campaign, but that it should not be given prominence.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

The MACC provides some guidelines for press releases to the lay media in relation to prescription-only medicines. A product-specific media release must be educational and may include a non-comparative description of the mechanism of action, price to the patient or date of product/indication availability. However, it must not include promotional statements or claims, comparisons with other products, quotes from experts, opinion leaders or patients that are promotional or comparative in nature or images of product packaging.

A product specific media release must contain all of the following in the main body of the release:

- the product's brand name;
- the Australian Approved Name of the active ingredients in the product;
- its approved indications;
- therapeutic class;
- PBS listings and restrictions, or a notation if the products are not listed on the PBS; and
- a summary of the side effect profile, product's precautions, adverse effects, warnings, contraindications and interactions consistent with the Minimum Product Information.

There were two decisions of the Medicines Australia Code of Conduct Committee in 2015, which make it clear that the Committee is applying these requirements increasingly strictly.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Background information relating to prescription-only medicines or research initiatives for prescription-only medicines are permitted under the TG Act, TG Regulations and the TGAC, provided that the information is not intended to promote the use or supply of those products. Information may also be included in disclosures to the Australian Securities Exchange, where required.

The ASMI Code of Practice contains some general provisions relating to the advertising of non-prescription medicines. Any background information on products and research initiatives which are published in corporate brochures or annual reports must comply with the ASMI Code of Practice.

Lastly, it is important to ensure that the representations being made in relation to the products or research initiatives of the company are not in breach of section 18 of the ACL.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

MACC contains rules which apply to company involvement with patient support groups. They provide that companies must ensure that activities associated with the patient support groups are not considered as promotional, and that no incentives are provided to patients to participate in these programmes, other than material that will enhance positive health outcomes and compliance.

Section 14 of the MACC also contains rules for how companies interact with Health Consumer Organisations ("HCOs"). These relationships are permitted and recognised as beneficial for enhancing the quality use of medicines by the Australian community, and the interaction between these bodies is also quite strictly controlled. A set of guidelines, Working Together – A Guide to Relationships between Health Consumer Organisations and Pharmaceutical Companies, has been developed to govern relationships with HCOs.

A company may also undertake to sponsor a patient or HCO representative to attend a third-party scientific or medical conference, where that attendance is based solely on their specific interest in a particular therapeutic area. Clear guidelines must be developed to govern these relationships.

Furthermore, on 30 April 2014, companies were required to submit to Medicines Australia their first annual reports identifying the HCOs they support. Such information will be published on Medicines Australia's website.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

A prescription pharmaceutical company may provide items for the benefit of patients, provided that those items satisfy the requirements for a Patient Support Program set out in section 17 of the MACC. There are a number of specific requirements for a Patient Support Program, but section 17 summarises those requirements as follows:

> "*Patient Support Programs may only be offered to patients who have already been prescribed a prescription-only Product. The healthcare and wellbeing of patients must be*

*the objective of a Patient Support Program. The obligation to be open and transparent about the conduct and management of a Patient Support Program is also central. This obligation is the basis for the requirement to communicate to patients about any payments that are made to a healthcare professional in association with a Patient Support Program.*"

A company must develop a clinical rationale for each Patient Support Program.

There are no specific provisions about Patient Support Programs in the MTIC, but the MTIC does contain the following general statement about providing benefits to patients:

"*MTAA recognises and supports relationships between Industry and Health Consumer Organisations, government bodies and other independent bodies having an interest in Consumer education in relation to Medical Technologies, which are used by Consumers for the sole purpose of facilitating education of Consumers and enhancing their quality use of those products.*"

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

There is no obligation on companies to disclose the details of clinical trials being conducted in Australia.

Australia does have a clinical trial registry (which also relates to New Zealand clinical trials), called the Australia New Zealand Clinical Trials Registry, which can be found online at anzctr.org.au. This registry is operated by an independent not-for-profit organisation. Registration of clinical trials is voluntary, but if a company chooses to register a clinical trial then the funding source for the trial must be disclosed.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no legislative requirement, but please see the answer to question 7.3.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Yes. Edition 18 of the MACC introduced a transparency regime for transfers of value to healthcare professionals by prescription pharmaceutical companies. The regime applies to all Medicines Australia members and in respect of activities that are "related to prescription medicines". This would include activities in respect of medicines not yet granted marketing authorisation. From 1 October 2015, companies are required to disclose on their website all transfers of value made to healthcare professionals (or to third parties at the request of a healthcare professional). The disclosure must include the identity of the healthcare professional and details about the circumstances of the transfer. The only exceptions are fees paid to conduct clinical trials and fees for market research, where the market research is conducted by a third party and the company itself is not aware of the identity of the healthcare professionals chosen to participate.

Such disclosure must be made twice a year.

There is no similar regime for medical device manufacturers.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Section 41.3.2 of the MACC requires a company to obtain appropriate consents from a healthcare professional to the disclosure of transfers of value. If a company does not obtain those consents it is in a difficult position because it will be breaching Australian privacy law if it discloses the transfer of value, but will be breaching the MACC if it does not. The practical answer is that a company should not make a transfer of value to a healthcare professional who has not provided the appropriate consents.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

The legislation contains a few special rules governing internet advertising. Internet advertisements are subject to the same regulatory regime as other advertisements for medicinal products (see question 1.1). As such, internet advertising of prescription-only medicines direct to the public is prohibited.

Internet advertising direct to consumers is possible for non-prescription medicines (except for certain pharmacist-only goods), and for medical devices. Those advertisements do not require prior approval, since the internet is exempt from the definition of "broadcast media" (regulation 5BA of the TG Regulations).

Websites available to the general public are often disease-centred, and do not provide product-specific information. A prescription pharmaceutical company may use the internet to provide to members of the public the following information:

- a brief non-promotional summary of the company's products available in Australia, in accordance with the current approved Product Information;
- in company disease state websites there should not be a focus on the company's products, although the company may choose to list all available treatment options (without making comparisons). Such a website should always include a statement to the effect that "for further information, speak to your doctor"; and
- a copy of each product's Consumer Medicine Information ("CMI"), a leaflet containing basic information about the use of a product, its contraindications and risks which the TG Regulations require companies to provide to consumers with each supply of a medicine.

Where a website includes information directed to healthcare professionals, this information should not be accessible to the general public (see question 8.2).

The MACC contains further detailed rules dealing with the use of the internet and social media to provide information both to the general public and to healthcare professionals.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

The MACC provides that any promotional information directed at healthcare professionals must be, "accessible only via a secure system that is designed to prevent access by members of the general public" (section 2.4.1).

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

It will depend upon the nature of the independent website, the relationship between its publisher and the company, and the context in which the link is provided. However, as a matter of general principle, there will always be a risk that the content of a linked website will be attributed to a company.

The MACC provides (section 13.9.2) that when making a reference or linkage to another information source, the company's website should, by virtue of a clear screen, make the following statements:

- the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should refer to the CMI for products to fully understand the terms of a product's registration in Australia;
- the intent of providing this material is informational and not as advice; and
- any information provided by this source should be discussed with the reader's healthcare professional and does not replace their advice.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Companies should take great care in placing information about their products on their website. Advertising of prescription products to the general public is prohibited, and the content of advertisements for other products is regulated. Given the broad definition of advertisement in the relevant legislation and codes, it is important to consider carefully whether a reference to a product on a website might amount to an advertisement.

However, it is common practice for Australian pharmaceutical companies to include on their website the names of their products and a brief description of their approved indications. As noted above in question 8.1, a pharmaceutical company may also include a copy of the product's CMI. Section 13.9 of the MACC provides specific guidance on the type of content that is permissible.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

To a limited extent. Clause 13.10 of the MACC deals specifically with social media. It requires that information provided to the general public via social media comply with a number of other relevant provisions of the MACC. It also provides that:

- companies are responsible for all content on company-initiated or controlled social media sites;
- companies must have policies and procedures which govern their employees' interactions on social media so as to ensure compliance with the MACC; and
- companies must report all adverse events which they note during monitoring of social media sites.

Other codes contain references to social media but no special obligations in relation to it. However, in November 2013, ASMI published guidelines for the use of social media by the self-medication industry.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

There have been significant changes to the regulation of advertisements for therapeutic goods directed at the general public. These include the introduction of a new Therapeutic Goods Advertising Code with effect from 1 January 2019 and the abolition of the Complaints Resolution Panel (which formerly heard complaints about advertisements directed at the general public). The TGA has now taken direct responsibility for the regulation of advertising (other than advertising directed at healthcare professionals). It can be expected that the TGA will be far more proactive in taking action in respect of breaches of the TGAC.

In November 2018, the TGA commenced proceedings against Peptide Clinics Pty Ltd for breach of a number of provisions of the TG Act, including the prohibition on advertising prescription-only medicines to the general public.

The TGA has also published the Australian Regulatory Guidelines for Advertising Therapeutic Goods which contains information about how the TGA will use its enforcement powers (https://www.tga.gov.au/sites/default/files/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg.pdf).

In addition, the Minister responsible for the administration of the Code of Conduct has established a Therapeutic Goods Advertising Consultative Committee as a forum where views can be sought from relevant stakeholders.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

The changes outlined in the answer to question 9.1 have occurred as part of a structured programme for the reform of advertising regulation.

It is proposed that for all advertisements for therapeutic goods directed at the general public, the various delegations of complaints handling functions to industry bodies will be withdrawn and the TGA will assume responsibility as a single body for all complaints related to advertising to the general public.

In addition, the *Therapeutic Goods Amendment (2017 Measures No 1) Act 2018* (Cth) contains provisions which will remove the requirement for pre-approval of certain advertisements, but which do not come into effect until 1 July 2020.

Finally, Medicines Australia proposes to introduce a new version of the MACC in 2020. Its consultations with members began in April 2019. It is reported that the new Code will be substantially different from the existing Code in that it will adopt a principles-based approach to regulation, meaning that many of the very prescriptive provisions in the existing Code will disappear.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

The major enforcement trend is that identified in the answer to question 9.1 above; namely the centralisation of regulation of advertising within the TGA, a step which is expected to lead to an increase in the level of enforcement activity.

It is also of interest to note that the level of complaints in the Medicines Australia complaints' resolution process is historically low. Indeed, the last complaint determination by the Code of Conduct Committee was in quarter 4 of 2017, meaning that for the first time on record, there have been no complaints determined for over a year. There were only two complaints received by Medicines Australia subsequent to that complaint, both of which were against non-member companies who declined to participate in the Medicines Australia complaints resolution process.

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# Austria

Herbst Kinsky Rechtsanwälte GmbH

Dr. Sonja Hebenstreit

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The laws and codes of practice that govern the advertising of medicinal products in Austria are the following:

- The Medicinal Products Act, "*Arzneimittelgesetz*" (in the following referred to as "AMG"), BGBl No 195/1983, as last amended by Federal Law Gazette (in the following referred to as "BGBl") No I 59/2018, sections 6 and 50–56a.
- Section 351g paragraph 5 of the General Social Security Act ("*Allgemeines Sozialversicherungsgesetz*" – in the following referred to as "ASVG"), BGBl No 1955/189, as last amended by BGBl No I 8/2019.
- The Unfair Competition Act ("*Gesetz gegen den unlauteren Wettbewerb*" – in the following referred to as "UWG"), BGBl No 1984/448, as last amended by BGBl No I 109/2018.
- The Austrian Pharmaceutical Industries Association's ("Pharmig") Code of Conduct, in its current version of July 1, 2015 (in the following referred to as "Pharmig CoC").

### 1.2 How is "advertising" defined?

Section 50 AMG defines "advertising" and mainly reflects the wording of section 86 of Directive 2001/83/EC (as amended).

According to section 50 paragraph 1 AMG, "advertising of medicinal products" shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

- the advertising of medicinal products to consumers (lay advertising);
- the advertising of medicinal products to persons qualified to prescribe or supply them (expert advertising);
- visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;
- the supply of samples;
- the provision of inducements to persons qualified to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and
- payment of travelling and accommodation expenses, as well as attendance fees in the context of occupation-related scientific events for persons qualified to prescribe or supply medicinal products.

Section 50 paragraph 2 AMG explicitly excludes the following cases from the rules restricting advertising:

- correspondence, possibly accompanied by material of a non-promotional nature, which is needed to answer a specific question about a particular medicinal product;
- trade catalogues and price lists, provided they include no product claims; and
- information relating to human health or diseases, provided that there is no reference, even indirectly, to medicinal products.

Finally, section 50 paragraph 3 AMG provides that the advertising restrictions shall not apply to the approved summary of product characteristics, labelling and patient instructions for use if these are used in line with AMG.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no explicit requirements to provide for specific compliance arrangements in the AMG or in the Pharmig CoC.

However, section 56 AMG obliges the authorisation holder to ensure:

- that any promotion for its products complies with sections 50 to 56a AMG;
- that its medical sales representatives comply with the qualification requirements (section 72 AMG) and their obligations laid down in section 73 *et seq*. AMG; and
- all distributed promotional material is available and a register of all addressees and distribution ways is maintained.

Further, the authorisation holder has to nominate a person within the company who is responsible for the scientific information about the medicinal products distributed by the respective authorisation holder ("*Informationsbeauftragter*"). This person needs to be equipped with the necessary powers of such position. In practice, all promotional material will need a "sign off" by the qualified person (section 56 AMG).

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

There are no explicit requirements for companies to have SOPs on advertising activities in place. However, as there are a number of requirements to be fulfilled (see sections 3 and 6 below), it seems advisable (and is common in the industry) to establish such SOPs (see question 1.6).

However, there is a requirement to employ personnel with a specific role: as stated in question 1.4, the authorisation holder has to nominate a person to ensure that any promotion for its products complies with the rules regarding advertising ("*Informationsbeauftragter*").

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

In Austria, no prior approval by any authority is needed for the advertising of medicinal products, either in general or in any specific situation. Furthermore, the law does not provide the authority with a specific right to require the companies to have their promotional material approved in advance by the authority; however, such right could eventually be deducted from the authority's rights mentioned in section 56a AMG.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The Austrian Federal Office for Safety in Health Care ("*Bundesamt für Sicherheit im Gesundheitswesen*", in the following referred to as "BASG") is entitled to take all necessary measures to restore a situation conforming to the law in case it finds during an audit according to section 56a paragraph AMG or otherwise gets to know that the advertising restrictions are violated, i.e. the BASG is also entitled to stop further publication of the advertisement in question. However, the law does not entitle the BASG to ask for a corrective statement. Against such measures, which would usually be taken in the form of a decision ("*Bescheid*"), an appeal is admissible.

Violations of the advertising restrictions further constitute an administrative offence (administrative penalty of up to €25,000 or even €50,000 in case of a repeated offence). Against decisions in this context, an appeal is admissible.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

A violation of the advertising restrictions contained in sections 50 to 55b AMG constitutes an administrative offence and penalties amounting to €25,000 or €50,000 (the latter in the case of a repeated offence) can be imposed. Please note that the responsible authority for the imposition of such penalties is not the Federal Office for Safety in Health Care, but the respective regional administrative authority ("*Bezirksverwaltungsbehörde*").

Moreover, according to section 85 AMG, the BASG may withdraw a marketing authorisation if a company has been punished three times for violating the advertising restrictions of the AMG.

The repeated violation of these regulations may also result in the withdrawal of the whole trade licence of the company. We are not aware of any major proceedings against pharmaceutical companies in this respect.

The predominant amount of cases of violations of the advertising restrictions are challenged by competitors and brought before the civil (commercial) courts. Any violation of the advertising restrictions constitutes a violation of section 1 UWG and the competitors can claim forbearance, (eventually, as the case may be) payment of damages and publication of judgment. Usually, the respective action is filed together with the application for rendering a preliminary injunction.

Furthermore, a number of institutions, *inter alia*, the Federal Economic Chamber, the Federal Chamber of Labour, the Main Association of Austrian Social Security Institutions, the Austrian Patient Advocacies, the Association for Consumer Information ("*Verein für Konsumenteninformation*"), the Pharmig, the Austrian Medical Association and the Austrian Pharmacists Association, are entitled to sue undertakings for violation of the advertising restrictions based on section 85a AMG.

Finally, the industry association Pharmig has implemented its own procedure: the Pharmig Committees of Experts of the 1st and 2nd Instance are in charge of negotiating and deciding in the case of disputes relating to the violation of the Pharmig Code of Conduct as far as Pharmig Members are concerned. The Pharmig Committee of Experts of the 1st Instance is entitled to impose the following sanctions in addition to the admonition and the cease-and-desist order: (a) in the case of a serious violation, a penalty of not less than €5,000, up to a maximum of €100,000 (and €200,000 in the case of repeated violations); (b) the violation may be publicly announced and the company concerned named in a Pharmig publication; (c) the parent company of the company concerned will be notified accordingly; (d) the Secretary General of EFPIA will be notified accordingly; and (e) exclusion from Pharmig or termination of the Pharmig Agreement.

The Code provides for a right of appeal against decisions of the Pharmig Committee of Experts of the 1st Instance.

To sum up, the predominant amount of cases are raised with the courts by competitors based on the UWG (in connection with the AMG) or by institutions (the Association for Consumer Information continues to be particularly active in this field) based on section 85a AMG.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

There is no legal relationship between the self-regulatory body of Pharmig and the authorities competent for supervision and enforcement of the advertising regulations, i.e. any decisions of

Pharmig are neither binding, nor otherwise relevant for the authorities. The competent authorities – namely the BASG and, in case any administrative offence procedure is opened, the respective *Bezirksverwaltungsbehörde* – will, in any case, investigate matters drawn to their attention on their own. Please note in this context that, according to Article 6.2.c of the Pharmig Code of Procedure of the CoC Committees of Experts of the 1st and 2nd Instance (forming an integral part of the Pharmig CoC), a complaint with Pharmig is inadmissible if the object of the complaint is also the object of pending court proceedings.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

As mentioned in question 1.7 above, violations of the advertising restrictions can be challenged by competitors and brought before the civil (commercial) courts. Any violation of the advertising restrictions constitutes a violation of section 1 paragraph 1 No 1 and/or No 2 UWG (and, eventually, section 2 UWG) and the competitors may claim forbearance, (eventually, as the case may be) payment of damages and publication of judgment. Usually, the respective action is filed together with the application for rendering a preliminary injunction.

The plaintiff needs to be a competitor regarding the respective medicine for which unlawful advertising has been made.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

In principle, any promotion for non-authorised medicines is prohibited (section 50a paragraph 1 AMG), except in case of promotion to experts during scientific events if the majority of participants come from outside Austria (section 50b paragraph 2 AMG). There is no exception corresponding to section 50b paragraph 2 AMG in place for off-label information on an authorised medicine (e.g. on a new indication); one could in this case, however, argue with an *argumentum a maiore ad minus* as according to section 50b paragraph 2 AMG; even promotion for non-authorised medicines is permitted and therefore promotion for a non-authorised indication of an authorised medicine or for another product variant should be allowed under the same conditions too. Please note that the above view has neither been confirmed nor refused by case law so far, as the question has, for the time being, not been the object of a Supreme Court decision.

Furthermore, it is possible to make available non-promotional information as a response to a (documented) specific question on the respective medicine. Likewise, the discussion of such unauthorised products during scientific meetings (even if sponsored by a company) is possible as long as the provided information is not promotional and a genuine exchange of scientific information takes place.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

As any promotion for unauthorised medicines as well as off-label information is prohibited, no publications of a promotional nature are allowed. However, it is possible to provide promotional material on unauthorised medicines or off-label information during scientific events if the majority of participants come from outside Austria (section 50b paragraph 2 AMG, see the answer to question 2.1 above).

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Such press releases will, in general, be covered by the broad definition of "advertising" in section 50 paragraph 1 AMG. As none of the exceptions in section 50 paragraph 2 AMG apply, the issuance of a press release on an unauthorised medicine or containing off-label information will most likely violate section 50a paragraph 1 AMG.

Although there are differences depending on the target audience (advertising and information to healthcare professionals and to laymen) in general, there are no specific differences regarding press releases (see section 3).

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

It is possible to make available non-promotional information as a response to a specific question on the respective medicine. Otherwise, the prohibition to promote unauthorised medicines would be violated.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The *Ludwigs* case has not (yet) been reflected in Austrian legislation or practical guidance.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

There are no specific rules in Austria with respect to that situation; however, such information would most likely have to be regarded as promotion of unauthorised medicines/off-label promotion as it is obviously intended to enhance the sales of such product, and therefore such information is not admissible.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

First of all, it would be necessary to clarify if such involvement of healthcare professionals would not already violate the prohibition to promote unauthorised medicines (which will most likely be the case). In case the involvement is not already inadmissible as such, the general rules regarding cooperation with specialist circles and institutions laid down in section 8 Pharmig CoC apply, as no more specific guidelines exist in this respect.

Section 8.2 Pharmig CoC states the following rules for cooperation with physicians that would be relevant for such market research:

- Any service rendered by members of the specialist circles for pharmaceutical companies (e.g. for lectures, consulting, clinical trials, non-interventional studies) must serve the purpose of training/education, research, support of the healthcare system or be provided within the framework of scientific and specialist activities.
- A written contract must be concluded, clearly indicating the service and remuneration to be provided, as well as the scope, type and purpose of the service. Remuneration may only consist of money and must be proportionate to the service provided. Hourly fees may be agreed to compensate for the time spent in providing the service. Any expenses incurred, including travel costs, may be additionally reimbursed to an appropriate degree. Among other options, the fee schedule for physicians can be used to assess the proportionality of remuneration.
- The provision of services by members of the specialist circles must not be linked to any conditions relating to the recommendation, prescription or the administering of medicinal products.

Please note in this context that the regulation on non-interventional studies ("*Verordnung über die Meldepflicht von nicht-interventionellen Studien*", BGBl II 180/2010) applicable to non-interventional studies needs to be observed (see question 5.5 below) in the case the service refers to a non-interventional study.

Further, the companies need to consider the transparency requirements laid down in Article 9 Pharmig CoC (see section 7 below).

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Section 54 AMG requires that any advertising of a medicinal product directed to persons authorised to prescribe or supply medicinal products needs to contain, if such advertising appears in printed publications, via electronic media or by way of telecommunication, the essential information about the medicinal product in line with the Summary of Product Characteristics ("SmPC") in a clearly legible form.

Moreover, based on section 42 of the Austrian Regulation dealing with the Summary of Product Characteristics for Medicinal Products ("*Verordnung über die Fachinformation* (*Zusammenfassung der Produkteigenschaften* – "SPC") *für Arzneispezialitäten*", BGBl II 175/2008), advertising to professionals must include the following information:

- name, pharmaceutical form and dosage of the medicinal product;
- qualitative and quantitative composition;
- indications and contraindications;
- information on excipients;
- name and address of the authorisation holder;
- whether the product is only available on prescription;
- whether the product may only be distributed by pharmacies;
- whether the product can be disposed outside a pharmacy;
- information on the pharmaco-dynamic properties (active substance) of the product; and
- to what extent the product is covered by the provisions on narcotics.

With respect to precautions, special warnings, interactions with other medicinal products, and undesirable and addictive effects of the product, it is sufficient to provide a reference to the SmPC in the respective publication.

Moreover, according to section 55 paragraphs 2 to 4 AMG, all information contained in promotional material shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. Quotations, as well as tables and other illustrative matter taken from scientific publications for use in such material, shall be faithfully reproduced and the precise sources indicated. In the case of references to scientific publications, the essential content of the same shall be impartially described and the precise sources indicated.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Further to paragraph 6 AMG prohibiting any misleading advertising for medicines, section 50a paragraph 3 Nos 1 to 4 AMG needs to be observed, which requires that pharmaceutical advertising describes the property of the pharmaceutical product objectively and without exaggeration and does not contain information (in writing or figuratively) that:

- implies a property of the product exceeding its actual property;
- gives the misleading impression that a result can be expected regularly; or
- is not in accordance with the labelling, user information or SmPC; whereby promotional claims complementing the information contained in the labelling, user information or SmPC may be used in promotion to specialist circles (but not to lay persons) if they are compatible with and confirming or clarifying that information.

Section 50a paragraph 3 No 3 AMG has been amended and a new section 50a paragraph 4 AMG has been added following the ECJ's decision in C-249/09 (*Novo Nordisk AS vs Ravimiamet*). Therefore, in the context of advertising to specialist circles, reference may (again) be made to studies which are not mentioned in the SmPC as long as the requirements as set out above are met.

However, in the context of lay advertising (allowed for non-prescription requiring medicines), reference to studies not mentioned in the SmPC might not be allowed, as lay advertising may not contain any claims that go beyond the labelling, user information or SmPC (see section 6 below).

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

There are no restrictions in place relating specifically to such endorsements; the general restrictions apply (see questions 3.1 and 3.2 above).

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

The AMG does not contain any rules with respect to comparative advertising. However, any comparative claims need to be in line with the provisions of the UWG (see question 3.5 below). The presence of data of at least one head-to-head study is highly recommended, as the comparison of data from different studies in the context of comparative claims may easily be misleading.

(See the answer to question 3.1 above.)

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Comparative claims in advertisements are not regulated in the AMG. However, according to section 5.7 b) Pharmig CoC, pharmaceutical companies are not permitted to make reference to brands of competitors in their promotion, unless the reference is admissible according to UWG. As a consequence, comparative claims in advertisements are subject to section 2a UWG: comparative advertising is permissible, provided that it does not violate the rules on fair competition, especially by discrediting the competitor or misleading the addressed public.

Regarding the question of whether it would be possible to refer to a competitor's product that has not yet been authorised in Austria, we can hold that no case law has been issued yet, but it seems possible if the reference complies with section 2a UWG; in particular, the fact that the competitor's product has not yet been authorised needs to be clearly and visibly mentioned in order to avoid misguidance of the addressed public. Finally, please also consider the answer to question 3.4.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Section 7.8 Pharmig CoC specifically refers to this question and holds that if companies distribute speeches or discussion contributions held at an event, or reports on these, they must ensure that this information correctly expresses what was communicated at the event. The same applies if they commission other persons, media or companies to do this.

Further, in the case any such material has to be regarded as promotional, the requirements mentioned in the answer to question 3.1 above have to be met.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Neither the AMG, nor the Pharmig CoC contain specific rules on "teaser advertisements".

However, such advertisements must comply with the general requirements laid down (above all) in the AMG and the UWG if they already refer to a specific medicine.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

As Product A has been authorised for a certain indication in combination with another product and the SmPC refers expressly to this combined use, the holder of the marketing authorisation ("MA") for Product A is allowed to promote the combined use in accordance with the SmPC.

If the SmPC for Product B does not refer to the combination use of the two products, the combination use must in our view not be promoted by the holder of the MA for Product B, as such promotion would not be in accordance with the SmPC. In order to be able to promote the combination use, the SmPC for Product B needs to be adapted.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Section 58 AMG allows the provision of medical samples to physicians, dentists and veterinary surgeons (in the following a "recipient") if the following requirements are observed:

1. Samples may be supplied:
   - only free of charge;
   - in a package not larger (but smaller!) than the smallest package on the market and including a clearly legible and irremovable reference that the package is a free medical sample – not-for-sale ("*Unverkäufliches Ärztemuster*"); and
   - to physicians, dentists or veterinary surgeons upon their written request.
2. During a period of one year after first delivery, as many medical samples of a medicinal product as may be necessary to assess the treatment success of, at most, 10 patients may be provided; however, a maximum of 30 medical samples per recipient must not be exceeded. After the first year, two medical samples per request may be provided, however, they must not exceed the amount of five medical samples per proprietary medicinal product per year and per recipient.

Records must be kept of each medical sample delivered. Finally, the delivery of medical samples containing psychotropic or addictive substances is generally prohibited.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Section 55a paragraph 1 AMG prohibits the granting, offering or promising of gifts, pecuniary advantages or benefits in kind to persons entitled to prescribe or supply medicinal products unless they are inexpensive and relevant to the medical or pharmaceutical practice.

The above-mentioned rules do not in principle prevent the provision of giveaways by pharmaceutical companies, provided they have only a small value and are relevant to the medical or pharmaceutical practice of the recipient. Unfortunately, no case law or other guidelines exist that would clarify the amount of such "small value".

However, the CoC does not allow the provision of giveaways anymore, but – in contrast – states in its sections 11.2 and 11.3 that no advantages may be offered, promised or granted to healthcare professionals, unless they are allowed by other provisions of the CoC or by the law.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Austrian law does not contain regulations on the provision of gifts or donations of pharmaceutical companies to healthcare organisations.

In principle, gifts or donations to such organisations would be permitted if the gift or donation is provided for a specific purpose and it is not conditional upon the purchase or prescription of any of the company's medicinal products. The same is valid for the donation of equipment and funding of costs of medical or technical services. For any such provision of a gift or donation, a written contract should be concluded. Please note that it has to be carefully checked in each individual case – in particular, in the case of a public hospital being the recipient – whether the respective gift or donation is indeed provided to a public official ("*Amtsträger*") or an authorised person or employee ("*Beauftragte*"/"*Bedienstete*") and could therefore violate the Austrian anti-corruption regulations, in particular, sections 153a and 307 *et seq*. Austrian Penal Code ("*Strafgesetzbuch*", BGBl 60/1974, as latest amended by BGBl I 61/2012 with regard to anti-corruption regulations). In principle, these rules apply to all kinds of advantages; only section 153a requires an advantage which is *not just minor*, whereby case law regards advantages of less than EUR 100 as minor in this context.

In addition, section 8.5 Pharmig CoC contains the following regulations regarding donations and subsidies (see the answer to question 7.3 below for disclosure obligations):

- Pharmaceutical companies are permitted to make financial or material donations or provide subsidies to institutions, organisations or establishments which predominantly comprise members of the specialist circles, only for the purpose of training/education, research or support of the healthcare system or within the framework of scientific or specialist activities.

When making financial donations or providing subsidies, pharmaceutical companies are obligated to keep records which clearly list the donations or subsidies – and in particular the scope, type and purpose of the same – and the recipient of the donation or subsidy as well as the permission of the same to disclose the donation or subsidy provided by the pharmaceutical company. Donations and subsidies must be made accessible to the public on the internet in accordance with Article 9 CoC, unless they are inexpensive.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Such practice would only be possible if such medical or educational goods or services comply with section 55a paragraph 1 AMG, i.e. they are of a small value and relevant to the medical or pharmaceutical practice (which seems most unlikely); section 8.5 d prohibits any donations to an individual HCP. Furthermore, the general rules of fair competition and antitrust law need to be observed in this context.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Volume-related (cash) discounts to institutions (hospitals) are permitted by the AMG and the UWG. However, the general competition (antitrust) rules need to be observed.

When it comes to rebates in kind, please note that section 55b AMG prohibits the provision, the offering and the promise of such rebates to persons entitled to prescribe or supply medicinal products as far as medicinal products contained in the Code of Reimbursement ("*Erstattungskodex*") are concerned. However, according to the legislative materials, this prohibition shall not be valid for hospitals (i.e. for the legal entities standing behind those).

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

No. Such an offer as well as such commercial arrangements would violate the provisions of the AMG and the Pharmig CoC if addressed to persons entitled to prescribe or supply medicinal products; furthermore, it could also violate the more general rules of the UWG and of the Cartel Act.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Austrian law and the Pharmig CoC do not contain any specific rules referring to such situation. However, the offering of a refund scheme would most likely involve the statement that a treatment's success can be expected for sure or that no adverse effects arise and would therefore be likely to be violating sections 6 and 50a paragraph 3 AMG (misguidance).

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

As mentioned above, the granting, offering or promising of gifts, pecuniary advantages or benefits in kind to persons entitled to prescribe or supply medicinal products are prohibited by section 55a paragraph 1 AMG. The sponsoring of continuing medical education for a specific physician or pharmacist is likely to be covered by that prohibition, as it would not qualify as inexpensive if the exception in section 55a paragraph 3 AMG is not applicable: that provision allows that pharmaceutical companies bear reasonable travel and accommodation costs, as well as participation fees for persons entitled to prescribe or supply medicinal products regarding scientific events related to the participants' profession; the applicability of the exception has to be determined in each individual case. Article 7 Pharmig CoC contains more detailed rules regarding this issue (see the answer to question 5.1 below).

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The Austrian Penal Code ("*Strafgesetzbuch*", BGBl 60/1974, as amended by BGBl I 61/2012 with regard to anti-corruption regulations) contains anti-bribery rules applying to any advantages given to a public official ("*Amtsträger*") or an authorised person or employee ("*Beauftragte*"/"*Bedienstete*") in its sections 307 *et seq*. Austrian Penal Code. Physicians in a public hospital or physicians in private practice acting on the basis of a contract with the sick funds could be the subject of these prohibitions. The most relevant provisions are sections 307 (bribery), 307a (granting of advantages), 307b (granting of advantages for the purpose of inducement), 308 (forbidden intervention), and 309 (bribery of authorised persons or employees).

There is no formal interaction between the anti-bribery competent authorities (i.e. the public prosecution service and the penal courts) and the authorities competent for the enforcement of the pharmaceutical advertising rules. However, they might (as would any other authority) refer any circumstances they are made aware of to the public prosecution service in case they suspect that a criminal offence (e.g. a violation of the anti-bribery provisions of the penal code) is given.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Section 55a paragraph 3 AMG allows that pharmaceutical companies bear reasonable travel and accommodation costs, as well as participation fees for scientific events related to the participants' profession. These costs can only be paid for the respective persons entitled to prescribe or supply medicinal products (i.e. for speakers and attendees), but not for an accompanying person.

Section 7 Pharmig CoC contains more detailed rules regarding this issue. Section 7.2 Pharmig CoC states that leisure time activities and/or social programmes (e.g. theatre, concerts, sports events) for participants may not be financed or organised and that pharmaceutical companies are not permitted to take care of the organisation, nor assume the costs for travel, room and board, or expenditures for recreational activities.

Section 7.3 Pharmig CoC requires that the attendance of the participants, the programme and the scientific and/or technical content of the event implemented must be documented.

With respect to the venue of the event, section 7.4 Pharmig CoC holds that it must be appropriate for the purpose of the event, located in the home country and be chosen based on objective factors. The recreational value of a conference venue has no selection criterion.

The question of whether hospitality may be offered for an event taking place in another country is regulated in section 7.5 Pharmig CoC.

Section 7.5 Pharmig CoC defines *international events* as events at which the company organising and implementing the event or supporting the event or its participants has its registered office outside of the country in which the event venue is located. The organisation, implementation and/or support of international events or the assumption of costs for participation in these events is only admissible if:

- the majority of participants come from a different country than the country in which the member company is based; or
- the necessary resources or specialised knowledge are available at the event venue, and in view of this, there are appropriate logistical reasons for choosing a venue in a different country (in the case of recognised specialised congresses with international speakers or visits to the company's own scientific or production facilities abroad).

Section 7.5 b) Pharmig CoC holds that in such case, both the code of the country in which the company organising, implementing or supporting the international event is based and the code of the country in which the international event is taking place, shall apply.

In an ordinance issued in 2014 (VO 1/2014 to Articles 7 and 8), Pharmig has held that the only costs that may be paid by a company to participants include the participation fee as well as reasonable travel, food and accommodation costs. The ordinance further defines the costs for a meal of less than €75 (including tax and tips) per person and meal as reasonable.

In an ordinance issued on September 1, 2015 (VO 1/2015 to Articles 7.1–7.4), Pharmig obliges its members to require a confirmation from the congress organiser that the event is in line with the Pharmic CoC requirements and that support paid by the undertaking will only be used to pay for participation fees, travel, food and accommodation costs.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

See the answer to question 5.1 above – pharmaceutical companies may bear reasonable travel and accommodation costs, as well as admission fees for scientific events related to the participants' profession. The participant is not allowed to be paid for his time. Section 7.6 Pharmig CoC explicitly states that the invitation of persons as participants or speakers to such scientific events may not be made dependent on the recommendation, prescription or distribution of specific medicinal products.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

A pharmaceutical company will not be held responsible for the contents, and the general hospitality arrangements, of independent meetings where it just provides sponsorships to individual doctors to attend, but it is in any case responsible for individual sponsoring provided by it and the authority may (theoretically) challenge whether the event is indeed a truly scientific event relating to the profession of the sponsored individual.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

The law does not contain further guidance on this subject; in principle, the provision of services by HCPs to pharmaceutical companies is permitted if made in compliance with the legal provisions.

According to the Pharmig CoC, it is possible to pay healthcare professionals ("members of specialist circles" according to the Pharmig CoC) for the provision of expert services under the following conditions (section 8.2 Pharmig CoC):

- any service rendered by members of the specialist circles for pharmaceutical companies (e.g. for lectures, consulting, clinical trials, non-interventional studies) must serve the purpose of training/education, research, support of the healthcare system or be provided within the framework of scientific and specialist activities;
- a written contract must be concluded, clearly indicating the service and remuneration to be provided, as well as the scope, type and purpose of the service. Remuneration may only consist of money and must be proportionate to the service provided. Hourly fees may be agreed to compensate for the time spent in providing the service. Any expenses incurred, including travel costs, may be additionally reimbursed to an appropriate degree. Among other options, the fee schedule for physicians can be used to assess the proportionality of remuneration;
- the provision of services by members of the specialist circles must not be linked to any conditions relating to the recommendation, prescription or the administering of medicinal products; and
- the member of a specialist circle shall not be granted, offered or promised any remuneration or benefit in kind to ensure that he/she agrees to receive a medical sales representative or accept information from other staff members.

Visits to members of the specialist circles and hospitals should not seem importunate with regard to frequency and the manner in which they are conducted. Employees who work as medical sales representatives must be obliged by their pharmaceutical companies to observe the standard practices in the trade.

Please note that such contracts with healthcare professionals would need to be disclosed in accordance with section 9 CoC.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes, if the requirements mentioned in the answer to question 5.4 above are met, the AMG does not contain specific legal rules governing such studies except for the definition of such "non-interventional studies" contained in section 2a paragraph 3 AMG.

Pharmig adopted an ordinance on non-interventional studies in March 2010 which contains more detailed requirements regarding such studies (regarding their content and documentation). Non-interventional studies also need to be notified with the BASG in accordance with the requirements described in the regulation on non-interventional studies ("*Verordnung über die Meldepflicht von nicht-interventionellen Studien*", BGBl II 180/2010, as amended). Among others, the names of the doctors taking part in the study, as well as a template of the contract to be concluded with these physicians, including the intended payments, need to be notified with the authority (section 5.2 of the regulation on non-interventional studies). The BASG has to keep an electronic register about all non-interventional studies notified. The company responsible for a non-interventional study has to provide the BASG with an executive summary report of the study, which will be provided to the general public on the internet (sections 4 and 7 of the regulation on non-interventional studies).

Please note that such contracts with healthcare professionals would need to be disclosed in accordance with section 9 CoC.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

It would at first have to be determined if such service serves the purpose of training/education, research, support of the healthcare system or is provided within the framework of scientific and specialist activities (section 8.2 a) Pharmig CoC). If this can be answered in the affirmative, it would be necessary to determine whether the other requirements of section 8.2 Pharmig CoC are met (see the answers to questions 5.4 and 5.5 above).

Please note that such contracts with healthcare professionals would need to be disclosed in accordance with section 9 CoC.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes. Sections 50a, 52 and 53 AMG contain the requirements that need to be followed.

The general rule to follow is that any pharmaceutical advertising has to describe the properties of the medicinal product objectively and without exaggeration (section 50a paragraph 3 AMG). It must not contain information (in writing or figuratively) that:

- implies a property of the product exceeding its actual property;
- gives the misleading impression that a result can be expected regularly; or
- is not in accordance with the labelling, user information or SmPC or goes beyond these (see question 3.1 above).

Section 50a paragraph 3 No 4 requires that lay advertising may not contain any claims that go beyond the labelling, user information or SmPC.

Section 52 paragraph 1 AMG requires that lay advertising must be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product.

Lay advertising may refer to the marketing authorisation or registration if such reference is not apt to create a false impression among consumers regarding the safety and efficacy of the respective medicine.

The provision of samples is prohibited, as well as sweepstakes in connection with the supply of medicines.

Lay advertising needs to contain the following minimum information (section 52 paragraph 2 AMG):

- the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;
- the information indispensable for correct use of the medicinal product; and
- an express, legible invitation to carefully read the instructions on the package leaflet or on the outer packaging, as the case may be.

Lay advertising for traditional herbal medicinal products need to contain the additional written information that the respective medicine is a herbal medicine for use in the specific indications exclusively based on the long-term use of the said medicine (section 52 paragraph 3 AMG).

Regarding "reminder advertising" (advertising exclusively consisting of the name of a medicinal product) to the general public, section 52 paragraph 4 AMG states that such does not need to contain all information relevant for the appropriate use of the medicinal product as required for "normal" advertising. If the "reminder advertising" appears on posters, printed advertisements or via acoustic or audio-visual media, a clearly perceivable reference to the fact that the medicinal product may also cause undesirable effects and that the instructions for use must therefore be carefully observed or the advice of a physician or pharmacist followed, shall be included.

Lay advertising shall not contain any elements which (section 53 paragraph 1 AMG):

- contain pictorial representations in connection with healthcare professionals or institutions of public healthcare;
- give the impression that a medical consultation or surgical operation is unnecessary, in particular, by offering a diagnosis or by suggesting treatment by mail;
- suggest that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
- suggest that the normal good health of the patient can be enhanced by taking the medicine;
- suggest that the health of the patient could be affected by not taking the medicine;
- is directed exclusively or principally at children;
- refer to a recommendation by scientists, healthcare professionals or persons who, because of their celebrity, could encourage the consumption of medicinal products;
- suggest that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggest that the safety or efficacy of the medicinal product is due to the fact that it is a "natural product";
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refer, in improper, alarming or misleading terms, to claims of recovery;
- use, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof; and
- indicate that a medicinal product requiring a prescription is available by distance selling.

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No. Section 51 paragraph 1 AMG prohibits advertising prescription-only medicines to the general public, with the only exception being vaccination campaigns organised or supported by the state, a province or a municipality.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Section 50 paragraph 2 No 3 AMG exempts information about the health or diseases of human beings and animals from the definition of promotion, provided that no reference is made, whether directly or indirectly, to a specific medicinal product.

A Supreme Court decision (4 Ob 96/14t) has qualified a vaccination campaign (not state-organised) as non-promotional disease awareness therewith indicating a broader interpretation of the term disease awareness than in the past. However, the question of whether such campaign can indeed be qualified as non-promotional has to be decided on a case-by-case basis.

### 6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

No. Such press releases will generally have to be regarded as unlawful promotion.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Article 4.1 e) Pharmig CoC exempts company-related information, e.g. to investors or current or future employees, including financial data reports on research and development programmes, as well as information on regulatory developments concerning the company and its products.

The AMG does not contain any rules on that question and there is no case law available in this respect. However, in the case the respective provision of information is required by other legal provisions, such provision of information will not violate the AMG, as long as any promotional tone is avoided.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

The AMG does not contain any specific provisions in this respect; however, such rules have been implemented in Article 10 Pharmig CoC.

Patients' organisations are defined as "voluntary, non-profit orientated associations, which predominantly comprise patients and/or their families and/or patient organisations, which solely represent the interests of patients and/or their families and exist or were founded out of their interests". Support is deemed to be "any financial contribution as well as any indirect contribution or any non-financial contribution" to patients' organisations.

The provisions of Article 10 Pharmig CoC do not apply to indirect contributions or non-financial contributions provided that they are of small value (without such small value being defined in the Pharmig CoC).

Section 10 paragraphs 1 to 8 Pharmig CoC require that:

- Any advertising with support of patients' organisations, as well as any use of logos or copyright-protected materials by pharmaceutical companies or patients' organisations, is subject to advertising restrictions per the Pharmig Code of Conduct and must be exercised exclusively on the basis of a written agreement per Article 9.3.
- Any support of patients' organisations shall serve solely the interests of the patients and/or their families.
- The exclusive support of patients' organisations and/or their programmes must not be agreed by pharmaceutical companies and/or granted by patients' organisations.
- Any support may only be provided on the basis of a written agreement.
- This agreement shall contain comprehensive information about the type, scope and purpose, as well as a description of the support involved and the consent of the patients' organisations, to disclosure by the pharmaceutical companies in accordance with Article 9.6. The value of the support must also be detailed.
- Pharmaceutical companies shall ensure that patients' organisations disclose to the public the relevant support provided by pharmaceutical companies transparently at all times and clearly from the outset.
- Services provided by patients' organisations to pharmaceutical companies must only be supplied for the purpose of training/education, research, support of the healthcare system or within the framework of scientific or specialist activities and based on a written contract; the remuneration must be appropriate and must constitue fair market value.
- Service agreements must obligate the patients' organisations to disclose their activities in full, where verbal or written public notifications of the patients' organisations refer to the subject or contents of the service agreements or, in general, to the pharmaceutical companies.
- Conclusion of an agreement regarding the provision of services must not be linked to the recommendation of certain medicinal products.
- Agreements regarding the provision of services by the pharmaceutical companies to the patients' organisations must be concluded in writing – unless they are inexpensive.
- The cooperation between pharmaceutical companies and patients' organisations must be transparent in nature.

Specific rules concerning the invitation of members of patients' organisations to scientific events are observed.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The AMG does not contain a general prohibition to provide advantages to patients (except regarding the prohibition to provide medicines to the patient for free).

The general rules – no lay promotion for prescription-only products and no violation of the fair rules of competition – have to be observed. If the items are meant to be used with certain medicinal products, the supply of such items will most likely have to be regarded as lay promotion. Furthermore, Section 55a paragraph 1 AMG, prohibiting the granting, offering or promising of gifts, pecuniary advantages or benefits in kind to persons entitled to prescribe or supply medicinal products, needs to be observed.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Currently, no such obligation has been implemented in Austrian law. Regarding the Pharmig CoC, see the answers to questions 7.2 and 7.3 below.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Austrian law does not require pharmaceutical companies to disclose information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations – see, however, question 7.3 with regard to the CoC and question 5.5 with regard to non-interventional studies.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The Pharmig CoC provides for detailed rules on transparency and disclosure, which apply to all information, advertising and marketing activities for medicinal products implemented by a pharmaceutical company itself or on its behalf. It does not restrict the exchange of medical and scientific information during the development of a product before its authorisation in Austria.

1. Disclosure of transfers of value to healthcare professionals and/or institutions

   According to Article 9.2 CoC, pharmaceutical companies have to document and disclose any and all "transfers of value" granted to healthcare professionals and/or institutions. Disclosure has to be made for one calendar year; the obligation is due six months after the end of the respective calendar year.

   The duty to disclose relates exclusively to transfers of value in connection with:

   - research and development;
   - donations and subsidies;
   - events; and/or
   - services rendered and consulting provided, including expenses incurred.

   The CoC requires individual disclosure in principle for all types of transfers of value except for transfers for the purpose of research and development, where aggregate disclosure is sufficient.

   Disclosure at individual level (Article 9.4 CoC) shall comprise specific information identifying:

   - each healthcare professional and/or each institution; as well as
   - the total of the transfers of value granted throughout the reporting period regarding donations and subsidies, and events (whereby separate information as to which transfers have been made for admission and attendance fees as well as for travel costs and accommodation have been made), as well as services rendered and consulting provided, including expenses incurred, whereby the information to be disclosed has to be detailed as follows:
   - Aggregate (summarised) disclosure – without stating the names of the individual healthcare professionals and/or institutions – suffices if the relevant transfer of value relates to research and development, which includes the reimbursement of expenses for attendance at events in connection with research and development activities.
   - Furthermore, those transfers of value are to be disclosed in aggregate form where "legal reasons do not permit the names of individual healthcare professionals and/or institutions to be disclosed" (Article 9.5 CoC).

   In such cases, transfers of value have to be allocated to the relevant types and disclosed in aggregate form. Detailed information has to be provided on the total number of recipients as well as their percentage as compared to all recipients of transfers of value of this type and the aggregate amount attributable to the relevant category.

   As under data protection laws, a disclosure requirement in an industry code does not justify the publication of personal data of a natural person, the companies need to get the consent of its contracting partners (being natural persons) to such disclosure.

   In case the relevant data subject does not give his consent, only aggregate disclosure is allowed.

   The Pharmig CoC further contains disclosure obligations regarding "donation and subsidies" to healthcare organisations (section 8.5 Pharmig CoC) and regarding support to patients' organisations (section 10.6 Pharmig CoC).

2. Donations and subsidies to healthcare organisations (Article 8.5 Pharmig CoC)

   - Financial or material donations and subsidies to healthcare organisations (i.e. organisations or establishments which predominantly comprise of members of the specialist circles) are only permitted for the purposes of training/education, research or support of the healthcare system or within the framework of scientific or specialist activities.
   - When making financial donations or providing subsidies, pharmaceutical companies are obliged to keep records, in particular regarding the scope, type and purpose, as well as the recipient of donations and subsidies and its permission to disclose the donation or subsidy.
   - Donations and subsidies must be made accessible to the public on the internet, unless they are inexpensive.
   - Article 8.5 Pharmig CoC does not contain any further requirements regarding the time of disclosure and the kind of information to be disclosed, but globally refers to Article 9 Pharmig CoC.

3. Support to patient organisations (Article 10.6 Pharmig CoC)

   - All patients' organisations that receive support from a pharmaceutical company, or that have concluded services agreements with a pharmaceutical company, need to be listed on that company's website.
   - The above information needs to detail the type, scope and purpose of the support or the type, scope and purpose of the service, the total value of the financial contributions or non-financial contributions, as well as the total of the service charges per calendar year and per patient organisation. If no precise monetary value can be determined in the case of indirect contributions or non-financial contributions, then the advantage gained by the patients' organisations must be described comprehensively and in verifiable form.
   - Indirect contributions or non-financial contributions, as well as inexpensive service agreements, are exempted from the publication obligation.

All published details must be updated at least once a year (no later than by 30 June for the preceding respective calendar year). The CoC rules only apply to Pharmig members.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Only an aggregate disclosure is possible in such case (section 9.5 Pharmig CoC). For any further cooperation with the HCP, the companies need to decide whether they want to cooperate with a HCP refusing to agree to the disclosure of his data. Many companies have adapted their standard contracts and introduced an explicit consent of the HCP regarding the disclosure of personal data.

## 8 The Internet

### 8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Austrian law does not contain any provisions specifically regulating advertising over the internet; i.e. the normal rules apply accordingly.

In addition, the Pharmig CoC contains specific provisions regarding information and advertising via the internet in its Article 6. According to these provisions, companies are required, *inter alia*, to regularly check their websites for accuracy and update them and to clearly specify the name of the pharmaceutical company operating or supporting the website and which information on the website is addressed to expert circles and which to the general public.

Section 6.2 Pharmig CoC refers to information about the company provided on websites and states that websites may contain:

- information of interest to investors, the media and the general public; and
- financial data, descriptions of research and development programmes, information regarding regulatory matters which concern pharmaceutical companies and their products, information for future employees, etc.

Section 6.3 Pharmig CoC contains provisions on the information for patients and the general public:

- Information addressed to the general public and containing advertisements must comply with the applicable provisions of the AMG and of the Pharmig Code of Conduct.
- Websites may contain non-promotional information on the medicinal products sold by the company for patients and the general public (however, in accordance with the ECJ's decision in C-316/09 (*MSD Sharp & Dohme vs Merckle*), only the faithful reproduction of the packaging of the medicinal product, and the literal and complete reproduction of the package leaflet or SmPC would qualify as non-promotional information).
- The website may contain a link to the complete, unmodified evaluation report as published by the CHMP (Committee for Human Medicinal Products) or a competent national authority.
- The website may contain links to other websites containing reliable information on medicinal products (websites of authorities, medical research institutions, patients' organisations, etc.).
- Apart from the brand name, the International Non-proprietary Name ("INN") must also be mentioned.
- The website must always contain a reference to a physician or pharmacist for further information.

Finally, section 6.4 Pharmig CoC specifically requires that information for specialist circles is clearly indicated as such. Further, companies need to ensure that the access to this information is reserved exclusively to specialist circles.

The control of internet advertising mainly happens through competitors. We are not aware as to whether the authorities have been specifically active in controlling information provided over the internet so far.

### 8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

There are no specific legal requirements in place. However, in order to comply with the general advertising restrictions of the AMG, as well as with the specific internet provisions of the Pharmig CoC, a company must establish a reasonable "safe access system" for the pages directed to healthcare professionals.

### 8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

In the absence of specific regulations on the responsibility for links in the AMG, the general rules apply. The Pharmig CoC states that links containing reliable information on medicinal products (websites of authorities, medical research institutions, patients' organisations, etc.) are permitted.

The company is not responsible for the content of a website connected to its own by way of reverse linking.

Regarding links to other websites from a company-sponsored site, section 17 of the Austrian Act on E-Commerce ("*E-Commerce-Gesetz*", BGBl I 152/2001) states that a company which provides access to third-party information by means of an electronic link shall not be responsible for such information, if the company: (i) does not have actual knowledge of illegal activity or information and, as regards claims for damages, is not aware of facts or circumstances from which the illegal activity or information becomes apparent; or (ii) upon obtaining such knowledge or awareness, acts expeditiously to remove the electronic link. However, this "privilege" shall not apply if the person from whom the information originates is subordinate to or supervised by the company or if the company presents the third-party information as its own.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Any information available for the general public (lay persons) needs to comply with the general advertising restrictions (see section 6 above). Most companies provide restricted access to information on medicinal products to healthcare professionals on their websites, as the information and advertisement to the general public (lay persons) is strictly limited with regard to content and appearance (see question 6.1 above). Please also refer to question 7.1 above.

According to the ECJ's decision in C-316/09 (*MSD Sharp & Dohme vs Merckle*), the dissemination of information on prescription-only medicinal products on (generally accessible, i.e. including for lay persons) websites of a pharmaceutical undertaking is permitted if the dissemination:

- consists solely in the faithful reproduction of the packaging of the medicinal product, and in the literal and complete reproduction of the package leaflet or SmPC, as approved by the competent authorities; and
- is accessible on the website only to someone who seeks to obtain it.

Therefore, any information on such websites relating to a (prescription-only) medicinal product that has been selected or rewritten by the pharmaceutical undertaking, which can be explained only by an advertising purpose, is prohibited.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Currently, no specific legislation is in place regarding the use of social media, which means that the normal rules apply.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The relevant provisions of the AMG have not been amended since the last edition of this guide. The Pharmig CoC was last amended in July 2015.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No significant developments are expected; in particular, no amendment of the AMG relating to the advertising provisions is currently pending.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The Austrian civil courts continue to be the most important "controlling authority" with respect to the advertising restrictions of the AMG. Enforcement is therefore mostly driven by competitors and by one of the institutions entitled to sue companies for unlawful advertising in accordance with section 85a AMG, namely the "Consumers' Information Association" ("*Verein für Konsumenteninformation*"), who has a focus on combating unlawful promotion to lay persons.

The Austrian Federal Competition Authority has announced a sector inquiry of the pharma industry for 2017; in this context a closer look may also be taken on compliance with the rules on pharmaceutical advertising (in particular on sections 55a and 55b AMG); so far, only an interim report regarding the market of public pharmacies in Austria has been published.



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# Belgium

Olivier Van Obberghen

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Quinz

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products (for human use) is governed by (i) the Law on Medicinal Products of 25 March 1964 ("**LMP**") (in particular by articles 9 and 10), and (ii) the Royal Decree regarding information and advertising of medicinal products for human use of 7 April 1995 ("**RDAMP**"). The LMP and the RDAMP set forth the general legal rules applicable to the advertising of medicinal products in Belgium.

This contribution also devotes particular attention to the new Law of 18 December 2016 regarding various provisions on health, which entered into force on 23 June 2017 (the "**Sunshine Act**"). The Sunshine Act imposes a legal transparency obligation on pharmaceutical companies to document and annually disclose premiums and benefits granted to healthcare professionals, healthcare organisations or patient organisations (see below under question 7.2).

The LMP and RDAMP are supplemented by four main self-regulatory deontological codes issued by the following professional associations (i) **pharma.be**, a professional association of Belgium-based innovative pharma/EFPIA companies, (ii) **BACHI** (the Belgian Association for the Consumer Healthcare Industry) which focuses on over-the-counter medicines and healthcare products sold in pharmacies, (iii) **Mdeon**, a common platform between several professional associations and healthcare professionals/organisations, and (iv) **FeBelGen**, a professional association of Belgium-based generic drug companies. These self-regulatory codes are only binding on the members of the relevant professional association.

This contribution focuses on the general legal framework for the advertising of medicinal products (including the Sunshine Act) that applies to all pharmaceutical companies in Belgium. The abovementioned self-regulatory deontological codes (notably the pharma.be Code of Deontology, which is applicable to 90% of the Belgian innovative pharmaceutical companies) will be addressed if such deontological codes (i) provide additional input or insights to further interpret or better understand the general legal framework, (ii) include additional material obligations for their members, or (iii) organise relevant *a priori* or *a posteriori* approval or control procedures on pharmaceutical advertising.

Finally, please note that the LMP and the RDAMP make a clear distinction between the advertising of medicinal products towards the "general public" and towards "healthcare professionals". Within the scope of the LMP and the RDAMP, only medical doctors, dentists and pharmacists are considered "healthcare professionals". This means that nursing personnel are regarded as part of the general public. However, please note that under the Sunshine Act, also nurses, paramedics and hospital directors fall under the definition of "healthcare professional".

### 1.2 How is "advertising" defined?

Article 9 LMP defines advertising as "*any form of door-to-door information, canvassing activity or stimulation which is designed to promote the prescription, release, supply, sale or consumption of medicinal products*". Patient information leaflets, product labels and general information regarding health and disease areas with no direct or indirect reference to a medicinal product are, however, not regarded as "advertising". The same applies to so-called "solicited" medical information about a particular drug product that is given by a pharma company further to a specific request from a patient or a healthcare professional, as long as such information is strictly necessary to answer said particular request and does not contain unsolicited promotional content.

The abovementioned definition and exclusions provided in article 9 of the LMP are the same as in article 86 of Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use.

The definition is further supplemented by article 2, §2 RDAMP, in which specific examples of advertising are named, such as the provision of samples, visits to healthcare professionals, sponsorships of scientific conferences and incitements to deliver or prescribe medicines by providing financial or in-kind benefits.

The distinction between "medical information" (which is subject to less restrictions and rules) and "advertising" is often difficult to draw. The litmus test that is generally used to differentiate both types of communication can be used to question whether or not such communication *intends* to promote or enhance sales of a particular drug product.

Supervising authorities usually broadly interpret the definition of "advertising" and seem inclined to assume that *any* type of medical communication is of a promotional nature *unless* clearly proven otherwise.

Pharmaceutical companies that are confronted with borderline cases and decide to consider a communication as "scientific information" (as opposed to "advertising") often apply the following rules of thumb to *mitigate* the risk of a so-called "requalification" by the supervising authorities: (i) ensure that this communication emanates

from its medical affairs department (and not from a member of its sales team); (ii) limit this communication to strictly scientific data; and (iii) keep a written file that can demonstrate (if needed) the clear non-promotional intent of said communication (and the assessment made by the company prior to its launch). The mere implementation of these rules of thumb can of course never entirely eliminate the risk of such requalification.

**1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?**

Applicable laws and deontological codes have installed various mechanisms that require the *a priori* control of communications related to medicinal products:

- Certain communications to the general public on over-the-counter ("**OTC**") drugs should be notified to or receive the prior approval from the Ministry of Health (see question 1.5 below).
- Information and advertisements to healthcare professionals and the general public should always be ratified in advance by the qualified person (responsible for the information) designated by the company (see question 1.4 below).
- Pharmaceutical companies are required to adequately train sales reps who visit healthcare professionals (including the scientific aspects of the medicinal products).

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

According to article 13 RDAMP, any marketing authorisation-holding company must designate a qualified person (responsible for the information) who will be accountable for the advertising and for providing scientific information on medicinal products by said company. The qualified person should be a pharmacist or physician and registered with the Ministry of Health.

There are no relevant legal or code requirements to have specific SOPs in place to cover advertising activities.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

With regards to advertisements towards *the general public*, the applicable approval and notification procedure depends on the medium that is used for such advertisement.

If the advertisement is made on the radio and/or television, the company should obtain a prior approval (visa) from the Ministry of Health (article 16, §1 RDAMP). The decision regarding this prior approval will be made on the basis of advice from the Commission on the Supervision on Advertisement on Medicinal Products, which operates as an independent commission within the Federal Agency for Medicines and Health Products ("**FAMHP**"). The Ministry of Health has 45 days to make a decision (article 17, §5 RDAMP).

All other forms of advertisement of medicinal products to the general public (e.g., advertisements in a newspaper or on the internet), should be notified to the Ministry of Health 30 days prior to their publication (article 16, §2 RDAMP). Please note that the Ministry of Health may require the company to provide additional documents in the framework of such notification which could potentially postpone the notified advertisement. The Ministry of Health may also prevent any (intended) advertising if it is not in line with applicable legal requirements (see also below under question 1.6). Both the visa and notification require the payment of a retribution by the company (EUR 1,240 for the visa, EUR 248 for the notification) and are valid for a period of two years.

Prior notification to or approval by the Ministry of Health is not required for advertising towards healthcare professionals.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

According to article 24 RDAMP, the Minister of Health has various options and powers to stop the publication or broadcasting of an advertisement that is not in line with the LMD and/or the RDAMD (e.g., revocation of a granted visa, immediate order to terminate the advertising, issuing of a corrective statement). If the advertisement is made on the radio and/or television, the decision to stop will be made in consultation with the Commission on the Supervision on Advertisement on Medicinal Products.

Before a decision is made by the Minister of Health, the company must receive the right to be heard and to defend its case. The company can appeal the decision of the Minister of Health at the highest Belgian administrative court (*Conseil d'Etat/Raad van State*).

The deontological codes include similar measures. The so-called DEP Committee of pharma.be may, for instance, oblige pharma.be members to take corrective actions in case there is a breach of the applicable deontological rules (correction of the material, corrective communication towards *healthcare professionals*, etc.).

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Under Belgian law, breaches of the rules governing the advertising of medicinal products are penalised with criminal sanctions (fines and imprisonment). The public prosecution should first open (generally on request of the FAMHP) a file against the allegedly infringing company and a judge should convict said company before a penalty can be imposed. The FAMHP may, however, propose a settlement with the company instead of requesting the public prosecution to open a file. There is, partly as a consequence of the latter but also due to the fact that pharmaceutical professional associations have their own mechanisms to take corrective measures *intra muros*, very little case law available on the subject.

A criminal prosecution against a company can also be initiated by the public prosecution further to a complaint by a competitor. And, although direct actions by competitors before the court are not expressly organised under the rules governing the advertising of medicines, competitors can also initiate proceedings under general

torts law or for breaches of the Code of Economic Law of 23 February 2013 (the "**CEL**") that includes general market practices principles, e.g., if they believe that a company's advertising is misleading or creates unfair competition (see also below question 1.9).

The pharmaceutical professional associations also have a separate set of penalties which can be imposed on their members in case of a breach of the applicable deontological code. The Committee for Deontology and Ethics in the Pharmaceutical Industry (DEP Committee) of pharma.be may, for instance, impose various corrective, supervisory and financial sanctions on its members. Please note that it is also possible for individuals (e.g., patients) and competitors to submit a complaint against a pharma.be member at the Secretariat of pharma.be, for the attention of the Committee for Deontology and Ethics in the Pharmaceutical Industry, which shall rule on such complaints. An appeal can be brought before pharma.be's Chamber of Appeal.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The self-regulatory deontological codes should be considered as independent rules and means of enforcement. Notwithstanding the foregoing, the pharma.be Code of Deontology explicitly determines that no procedures can be started before the pharma.be deontological bodies if another procedure on similar grounds has already been conducted (in the past) before another competent authority. If a procedure is initiated before the deontological bodies of pharma.be and, during such procedure, a separate procedure is initiated before another competent authority, the decision by the pharma.be deontological body will be deferred until the other competent authority has made a decision (article 93 pharma.be Code). It is, on the other hand, possible that a deontological organisation notifies a breach by one of its members to the regulatory authorities or the public prosecution (this is, for instance, explicitly provided for in the pharma.be Code of Deontology). Regulatory authorities, courts or the public prosecution will only be competent to decide on a breach of a deontological code to the extent such also constitutes a breach of the applicable legal framework (notably the LMP and the RDAMP).

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Pursuant to the CEL (that includes general principles on market practices), pharmaceutical companies can initiate various actions to counter unfair competition. Possibilities include cease and desist procedures and the request for compensation for damages on the grounds of unfair competition.

In principle, any entity that suffered harm from an alleged unfair competition has legal standing to initiate any such proceedings.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

All advertising (including to healthcare professionals) of (i) medicines that are not yet authorised, or (ii) off-label indications, is expressly forbidden by article 9 LMP. This prohibition, however, only applies to advertisements and *not* to medical information (for the difference between both concepts, see above under question 1.2). Pharma companies may therefore, in general, provide information on non-authorised medicines or off-label indications to a healthcare professional to the extent that such information was *requested* by said healthcare professional.

It is also generally accepted that scientific information on non-authorised medicines or off-label indications (such as results of clinical studies) may be presented to healthcare professionals during scientific meetings, as long as such presentation is strictly scientific and is not (blatantly) intended to promote the relevant drug product. Such intention will be more difficult to disprove if the meeting is (materially) sponsored by the product owner and it is always preferable to have such presentations brought by an independent expert faculty.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Information on non-authorised medicines or off-label indications can be published in independent scientific (and non-commercial) magazines or journals (preferably peer reviewed). Such publication can, however, never be used as promotional material by a pharma company (e.g., by extending copies of said journal to a healthcare professional).

All other publications of non-authorised medicines or off-label indications will in principle be deemed promotional and therefore illegal.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Pharmaceutical companies should be very cautious with issuing press releases that refer to unauthorised products or off-label indications (e.g., by circulating updates on ongoing clinical trials or approvals outside the EMA) and as such, releases will likely be considered to have promotional intent in breach of article 9 LMP (regardless of the target audience).

The pharma.be guidelines are even stricter and consider that such press releases are *only* possible if they are made by journalists independently of any input from the pharmaceutical company (e.g., when the journalist has received the information during a scientific event organised by a third party).

It is, however, generally accepted that pharmaceutical companies give updates on their pipeline pharmaceutical products to the specialised media during the development or marketing authorisation phases (e.g., results of clinical trials). The pharmaceutical companies must, however, make sure that such press releases are drafted in such a manner that they cannot be considered as advertising. For instance, only objective and scientifically verifiable information should be provided and the non-proprietary name of the active pharmaceutical ingredient should be mentioned rather than the anticipated trade name of the product.

### 2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

See above under question 2.1. Information on non-authorised medicines or off-label indications may in principle only be sent to healthcare professionals upon their request.

### 2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

Article 9 LMP contains an explicit exception for the provision of price lists that contain no information about the medicinal product (except for the name). This exception was already included in article 9 LMP *before* the decision in the *Ludwigs* case.

### 2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

As set forth in question 2.1, such information to healthcare professionals is likely to be considered an advertisement on unauthorised medicines or indications in breach of article 9 LMP, unless this information was expressly solicited by said healthcare professionals.

### 2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

This is possible, provided that (i) the rules regarding consultancy services by healthcare professionals are respected (see below under question 5.4), and (ii) the applicable consultancy agreement was not solely entered into as a workaround to transfer information on unauthorised products or indications to healthcare professionals.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

Generally, *all* advertisements (to both the general public and healthcare professionals) must present the characteristics of the medicinal product in such a way that it (i) is compatible with the summary of the product characteristics (SmPC), and (ii) ensures a rational use thereof (article 9 LMP). In addition, the applicable legal framework and deontological codes provide that the presentation of a drug product in advertisements must (i) be accurate, up to date, objective, sufficiently complete, truthful, verifiable, and compatible with the most recent content of its marketing authorisation dossier, (ii) reflect the generally accepted scientific knowledge, and (iii) be backed up by bibliographical data.

Article 9 RDAMP further specifies that an advertisement in the press directed at *healthcare professionals* should contain the following essential data which should cover at least 50% of the total advertisement space: (i) the name of the product, its qualitative and quantitative composition in terms of active substances, as well as its pharmaceutical form; (ii) all information regarding indications, posology, contraindications and side-effects contained in the SmPC; (iii) the package leaflet or the labelling in case of a homeopathic medicinal product; and (iv) the (trade) name of the marketing authorisation holder as well as the number of the marketing authorisation or product registration. It must also contain the applicable retail price per approved formulation/pack size. Such price must appear in bold, on a contrasting background in the upper right-hand corner of the advertisement and should at least cover 0.5% of the print advertisement. Finally, the advertisement must explicitly mention the date of its creation or the date of its last revision.

For the sake of completeness, please note that pursuant, to article 5 RDAMP, certain means for the advertising of medicinal products (to both the general public and healthcare professionals) are prohibited, such as advertising by means of airplanes, billboards, telephone, SMS, fax, email, mailing, children's magazines, leaflets, contests, software programs, etc. Moreover, it is prohibited to promote medicinal products by promising, offering or granting any direct or indirect compensation if the patient is not satisfied with the product. Note that advertising by email, fax or mailing to healthcare professionals is *not* prohibited if said professionals have given their prior consent.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Pursuant to the LMP, all information included in an advertisement for medicinal products must comply with the information set out in the SmPC. Further to the European Court of Justice decision held in the *Novo Nordisk AS v. Ravimiamet* case (C-249/09; 5 May 2011), it is generally accepted that the inclusion in advertisements directed to healthcare professionals of information that is *not* part of the SmPC is allowed as long as such information confirms, clarifies or supplements (*i.e.*, does not directly or indirectly contradict) the specifications made in the SmPC and is not misleading.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Endorsements by healthcare professionals in promotional materials to other healthcare professionals are not expressly prohibited.

Such endorsements are only possible if the following conditions are met:

(i) all information contained in the endorsement is compatible with the SmPC;

(ii) the healthcare professional did not receive any premiums or allowances for said endorsement; and

(iii) the information included in the endorsement must be objective, truthful, and backed up by verifiable data.

Companies should therefore be cautious to include any endorsements in advertisements to healthcare professionals, as it will always be difficult to demonstrate that such endorsement is "objective" and "verifiable by data". The validity of such endorsements should therefore be checked on a case-by-case basis and should, in any event, be strictly limited to statements by key opinion leaders in the relevant therapeutic area who have conducted or were involved in scientific research concerning the relevant drug product.

Article 7 RDAMP, however, does prohibit the inclusion in advertisements to the *general public* of any recommendation by scientists, healthcare professionals or other persons who, because of their status, could encourage the consumption of medicinal products.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Under Belgian law, there is no such specific requirement. The general rules on comparative advertisement (as set forth below under question 3.5 below) should, however, be complied with. This means, *inter alia*, a comparative claim must be fair and may not be misleading.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Article VI.17 of the CEL lays down the requirements for legitimate comparative advertising. Comparative advertisements:

- cannot be misleading;
- should compare similar products;
- should compare one or more essential, relevant, verifiable and representative elements of the product (e.g., the price);
- should not create confusion between the advertiser and the competitor or between their brands, trade names or other distinguishing marks;
- must refrain from discrediting or disparaging the other company and its products/activities; and
- should not represent the products as being an imitation or counterfeit of products with a protected brand or trade name.

In addition, the pharma.be Code of Deontology states that comparative advertisements, if necessary or useful, must present the comparator product in a manner that is fair, complete, and based on the most recently available data.

Given the general prohibition of advertising of non-approved medicines or indications (as set forth above under question 3.1), comparisons with a medicinal product that has not been authorised should be deemed illegal *per se* (even if these are in line with the above requirements).

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

As set forth above under question 2.2, the distribution to healthcare professionals by a pharmaceutical company of scientific papers (or proceedings of congresses) that refer directly or indirectly to a drug product of said company will generally be considered as advertising and be subject to the same rules set out herein. Note that such distribution by pharmaceutical companies will also be subject to the rules related to gifts to healthcare professionals (see question 4.2 below).

Pharmaceutical companies should also avoid scientific papers (or proceedings of congresses) that refer directly or indirectly to a drug product of said company and distributed on a congress sponsored by the company, as this may also be considered as (indirect) advertising by the company.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Teaser advertisements that directly or indirectly refer to upcoming data about a drug product will be considered as advertising and be subject to the same rules set out herein (including the general prohibition to promote unauthorised products or indications).

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

As set forth under questions 3.1 and 3.2, all information included in an advertisement for a pharmaceutical product, whether directed to HCPs or to the general public, must comply with the information set out in said product's SmPC. Accordingly, it should be possible for the marketing authorisation holder of Product A to promote Product A for combined use with Product B, as long as any such claim is presented in an accurate, up to date, objective, sufficiently complete, truthful, verifiable, and faithful manner. Conversely, it would not be possible for the marketing authorisation holder of Product B to promote said combined use as no such marketing authorisation exists for Product B. The marketing authorisation holder of Product B must in other words first modify the SmPC for product B to include said combined use.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes. The provision of free samples is possible, provided that the rules and obligations of article 12 LMP and the Royal Decree of 11 January 1993 regarding medical samples are complied with. Further clarifications concerning these provisions are set out in Circular no. 503 of the FAMHP.

As a general principle, samples can only be provided to a HCP authorised to prescribe such product on his specific request, on the condition that for such medicinal products a marketing authorisation has been obtained in Belgium. The provision of samples is limited to eight samples per product (in its smallest available pack size) per treating physician per year. Furthermore, each HCP may receive no more than 600 samples, in total, per year.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Article 10 LMP contains a prohibition to provide gifts to HCPs, with the exception of gifts which have a limited value, and which are directly related to the medical profession (e.g., medical/pharmaceutical scientific reference work, scientific CD-ROM, writing instruments, clinical material, IT accessories for professional use, etc.).

During the parliamentary discussions on the LMP it was acknowledged that EUR 50 per gift per healthcare professional/healthcare organisation and a maximum of EUR 125 per healthcare professional/healthcare organisation per year would be considered as "limited value". Although these thresholds were eventually not explicitly provided for in the LMP, these amounts are considered as the standard within the entire sector (e.g., pharma.be also uses these amounts as the maximum amounts for all of its members).

It is not possible to give cash money to healthcare professionals, as this cannot be considered as "directly related to the medical profession".

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Article 10 LMP contains a broad prohibition to provide gifts to wholesalers, intermediaries, persons who are entitled to prescribe, dispense or administer medicinal products or to institutions where such prescription, dispersion or administration takes place. Strictly speaking, donations to healthcare organisations are not exempt from this prohibition.

In practice, however, it is possible for the industry to give donations (e.g., money to organise an activity, research equipment) to healthcare organisations for educational, humanitarian or philanthropic purposes. The pharma.be Code of Deontology further specifies that such donations are only allowed if these are made available for the purpose of supporting healthcare or research and if these do not constitute an inducement to recommend, prescribe, purchase, sell, supply or administer medicinal products. A typical example of a permitted donation is the support/sponsorship of a scientific congress organised by a healthcare organisation. As the scope of this exception is not entirely clear, it should be assessed on a case-by-case basis. Donations which relate to the day-to-day operations of the healthcare organisation (payment of the salary of the nursing personnel, renovation works in the hospital, etc.) should always be considered as borderline and treated with appropriate restraint.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

No. It is not possible for the industry to give any advantages that may lead to a change in prescribing patterns as a direct result thereof.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Discounts (including volume-related discounts) are permitted if they are in line with the (general) principles of economic law (in particular those included in the CEL) and applicable competition principles (including on abuse of dominance). The rules on advertisement and inducement may, however, still have an impact on the validity of certain discounts. It is, for instance, not possible to offer *free* authorised medicinal products (except in the case of samples).

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

The provision of additional services and of so-called "package deals" is to be considered an advantage that is related to the purchase of medicinal products, which are, in principle, prohibited by article 10, §1 LMP. However, depending on the circumstances (e.g. in the case an apparatus for administration of the medicine is offered), such advantages may arguably be considered as gifts of limited value which are directly related to the medical profession. As set forth under question 4.2, such advantages are exempt from the prohibition in article 10, §1 LMP.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

These refund schemes are explicitly prohibited by article 5 §1, 10 RDAMP. The prohibition of "not-satisfied, money back" practices applies both to prescription medicines and OTC medicines.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Pharmaceutical companies may both sponsor the attendance of healthcare professionals to continuing medical education (including hospitality) as the associations that organise such continuing medical education. Article 10 LMP, however, determines that said sponsoring is only possible if:

1) the event is exclusively scientific in nature;
2) the hospitality is strictly limited to the scientific objective of the event;
3) the location, the date, and the duration of the event do not create confusion about the scientific nature of the event;
4) the financial contribution to the participation, including the offered hospitality, is strictly limited to the official duration of the event; and
5) the coverage of the costs are strictly limited to healthcare professionals concerned by the event.

For events with an overnight stay, a prior visa should be obtained from Mdeon. Mdeon has also drafted additional guidelines regarding the hospitality that can be offered to healthcare professionals in the framework of a scientific event (e.g., cost of an overnight stay is limited to EUR 250, cost of lunch is limited to EUR 40, cost of a dinner is limited to EUR 80, travel within Europe should always be in economy class, etc.).

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Under Belgian Law, the rules on anti-bribery applicable to companies (private bribery) are provided in article 504*bis* and 504*ter* of the Belgian Criminal Code of 8 June 1867. The Central Anti-Corruption Department (*Centrale Dienst voor de Bestrijding van Corruptie/Office Central pour le Répression de la Corruption*), a department of the federal police, is responsible for the detection of bribery/corruption crimes. This department can investigate breaches of the anti-bribery legislation independently from the pharmaceutical authorities.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

As mentioned above under question 4.8, the provision of hospitality is governed by article 10 LMP (hospitality is only possible for scientific events) and the interpretation and implementation of this article by Mdeon. These rules apply to hospitality offered to Belgian healthcare professionals or healthcare professionals exercising their profession in Belgium, for scientific events both in Belgium and abroad. As set forth under question 4.8, the cost of a meal provided to a healthcare professional is limited to EUR 40 for lunch and EUR 80 for dinner.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Except for the provision of hospitality (registration fees, travel costs, accommodation), it is not possible to pay the healthcare professional as long as she/he does not perform any scientific services (see below under question 5.4). It is not possible to pay for the time of the healthcare professional if this time is not used for the provision of scientific services.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Although this is not explicitly provided for in article 9 LMP and the RDAMP, pharmaceutical companies may be held responsible for the contents distributed on scientific meetings organised by the company and/or sponsored by the company. For instance, if off-label information regarding a medicinal product of a company is distributed during a congress organised or sponsored by such company, it will be difficult to disprove that this off-label information is non-promotional. This is confirmed by the applicable pharma.be guidelines.

The above does not apply to information (including possible advertising) that is distributed during a scientific meeting attended by a healthcare professional to whom hospitality was provided but which is not sponsored or organised by the pharmaceutical company.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes. The services to be provided by healthcare professionals should be of a scientific nature and have a legitimate character. Possible services may include speaker engagements, participation in advisory boards, consultancy, clinical trial services, etc. Specific Mdeon guidelines provide that the compensation for the healthcare professionals should be (i) reasonable, (ii) proportional, (iii) consistent, (iv) a reflection of the "fair market value of the services, and (v) be in accordance with the scope and duration of the services" (e.g., in function of the complexity, level of experience of the healthcare professional, degree of urgency). The prescription behaviour of the healthcare professional should not be a factor for determining the applicable compensation. The provision of services by a healthcare professional can never be used as a means to provide (prohibited) advantages to healthcare professionals.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

This is possible if the post-marketing surveillance studies have a scientific nature and legitimate character (see above under question 5.4).

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

This is possible if the post-marketing surveillance studies have a scientific nature and legitimate character (see question 5.4 above). As promotional materials are involved, it is advised to clearly describe the scientific nature of the services before these services are provided by the healthcare professional.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, unless such advertisement: (i) gives the impression that a medical consultation or surgical operation is unnecessary; (ii) suggests that the effects of taking the medicinal product are guaranteed or that there are no side effects; (iii) suggests that the health of the patient can be enhanced by taking the medicinal product or affected by not taking the medicine; (iv) is directed exclusively or principally at children; (v) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing, but who – because of their status – could encourage the consumption of medicinal products; (vi) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product; (vii) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural; (viii) could lead to erroneous self-diagnosis; and (ix) uses improper, alarming or misleading terms or pictorial representations (see article 7 RDAMP).

Furthermore, article 8 RDAMP requires that advertising (for non-prescription medicinal products) directed to the general public should: (i) be set out in such a way that it is clear that the message is an advertisement; and (ii) include the following minimum information:

- the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;
- the information necessary for correct use of the medicinal product;
- the statement "*this is a medicinal product, no long term use without medical advice*";
- an express, legible invitation to carefully read the instructions on the package leaflet or on the outer packaging, as the case may be. In case of advertisements on the radio, such invitation must be explicit and clearly audible; and
- the (trade) name of the marketing authorisation holder.

Finally, please note that the principles and restrictions of article 9 LMP and article 5 RDAMP, as set forth above under question 3.1 are also applicable to advertisements of non-prescription medicinal products to the general public.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

No, this is expressly prohibited under Belgian law.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Yes. If such disease awareness campaign makes no direct or indirect reference to any medicinal product, it is considered "information", which falls outside the definition of "advertising of medicinal products" pursuant to the LMP (see also above under question 1.2).

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

As set forth above under question 2.3, press releases that refer, directly or indirectly, to medicinal products, will in principle be considered as an advertisement. Press releases concerning prescription-only medicines directed at non-scientific journals are therefore prohibited.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Since this material will be available to the general public, the general rules on advertisements set forth herein should be complied with.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

The LMP and RDAMP do not contain provisions on relations with patient organisations. A patient organisation that has a healthcare professional among its members should, however, be treated as a healthcare organisation to which article 10 LMP applies (see questions 4.2 to 4.4 above). Pharmaceutical companies should also be careful that their public interaction with patient organisations within a specific therapeutic area does not qualify as advertisement to the general public in respect of their related drug products.

Chapter 6 of the pharma.be Code of Deontology contains rules applicable to relations with patient organisations. Pharmaceutical companies may (i) provide financial support to a patient organisation, (ii) call on patient organisations for the performance of certain services aimed at the support of healthcare or research, or (iii) sponsor events organised by patient organisations to the extent that such support is covered by a written agreement.

Pharma.be requires its members to make the support it has attributed to patient organisations available to the public on a yearly basis. As set forth under question 7.2 below, this transparency obligation has been legally anchored into the Sunshine Act, making it incumbent on all companies (and not only those who are members of pharma.be).

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Advertisements through the provision of items (e.g., donation of a free scarf when buying cough syrup) is not possible, since article 5,6° RDAMP prohibits advertising through means destined to be used totally or partially for another purpose than the communication of information. It may, however, be possible to provide items to the benefit of patients, as long as this cannot be considered (directly or indirectly) as an advertisement for a *specific* pharmaceutical product. It might, for instance, be possible to provide a ballpoint (only) containing the name of the pharmaceutical company during a meeting with a representative (non-healthcare professional) of a patient organisation.

Notwithstanding the above, there is a growing consensus that providing items for free for the benefit of a patient's health within the framework of patient support programmes (e.g., starter-kits, education regarding the administration of the product, home care and follow-up apps) is acceptable. Currently, the FAMHP, the Minister of Health and pharma.be are drawing up guidelines relating to this practice (see also question 9.3).

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Besides the general European regulatory requirements for disclosure of the details of clinical trials to the regulatory authorities (e.g., to the "end of trial declaration"), there are no general obligations for pharmaceutical companies to disclose the results of a clinical trial to the general public.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Yes. This requirement is set out in chapter 1 of title 3 of the Sunshine Act.

The Sunshine Act imposes the legal obligation on pharmaceutical (and medical devices) companies, whether Belgian or foreign, to document and annually disclose on the platform betransparent.be the premiums and benefits that they granted directly or indirectly to healthcare professionals, healthcare organisations or patient associations.

The transparency obligation applies to (i) contributions to the costs of a scientific manifestation, (ii) fees for services and consultancy, and (iii) donations or grants provided to – as applicable – (a) healthcare professionals having a practice in Belgium, (b) healthcare organisations based in Belgium, or (c) patient organisations based in Belgium. Please note that within the scope of the Sunshine Act, "healthcare professionals" are defined as any natural person practising medical, dental, pharmaceutical, veterinary or nursing art or who, in the course of her/his professional activities, may prescribe, purchase, deliver, recommend, lease, use or administer medicines or medical devices and whose practice is established in Belgium. Hence, for the scope of application of the Sunshine Act, also nursing personnel are regarded as "healthcare professionals".

The provision of such premiums and benefits must be made public on an individual basis (on behalf of the recipient who received them directly or indirectly). Each company subject to notification must make public, for each beneficiary, the amounts of the premiums and benefits granted to that beneficiary during a calendar year (see also question 7.3).

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Yes. Multiple deontological organisations have together created the Belgian Transparency Register of betransparent.be, which is used for all disclosures under the Sunshine Act. As a general principle, the companies have an obligation to disclose, on a yearly basis (ultimately on 31 May of the year following the calendar year in which the transfer of value has been made) all transfers of value to healthcare professionals, healthcare organisations and patient organisations on an *individual* basis (note, however, the exception set out below under question 7.4). Please note that when a premium or benefit is granted to a healthcare professional *indirectly*, e.g. through a healthcare organisation or corporation, the disclosure should be made on the name of the healthcare professional.

The disclosure should include the following details:

1. the name and company number of the company subject to notification;
2. the name and company number/RIZIV-INAMI number of the beneficiary or any other number that allows the FAHMP to identify the beneficiary; and
3. the total amount of the attributed premiums and benefits in respect of the relevant calendar year.

At the end of June of each year, the premiums and benefits granted in the preceding calendar year will be made public on the betransparent.be platform. The published data remains public for three years and will be removed afterwards.

Before the entry into force of the Sunshine Act on 23 June 2017, the transparency obligations for pharmaceutical companies were *only* based on self-regulation and were hence only incumbent on companies bound by a self-regulatory code including such transparency obligations (such as the pharma.be Code). Now that the transparency obligations have been anchored in legislation, these are binding upon all companies within the pharmaceutical (and medical devices) sector (including pharmaceutical companies, importers, manufacturers and distributors), irrespective of whether they are based in Belgium or abroad.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Since the publication of the transfer of value (including the healthcare professional's personal data) takes place according to a legal basis in the Sunshine Act, an individual healthcare professional cannot object to the publication of the data mentioned in the law. Companies subject to notification should therefore not obtain prior consent to be able to publish this data in the Transparency Register. However, they must first inform the beneficiary of this publication in accordance with applicable privacy laws. This information is often provided by a clause in the contract between the company and the beneficiary.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

The aforementioned general rules for pharmaceutical advertising, particularly article 9 LMP and the principles of the RDAMP, also apply to internet advertising. The Law on Certain Legal Aspects of Services in the Information Society of 11 March 2003 (the "**E-Commerce Law**") contains further specific rules on electronic advertising (on a website, by e-mail or through any other electronic means). Pharma.be also issued guidelines regarding the mandatory information to be included in internet advertising.

In general, advertisements on a **website** by a pharmaceutical company must comply with the following rules: (i) the advertising must contain a clearly visible, legible and unambiguous statement that it is an advertisement; and (ii) the pharmaceutical company to which the advertisement relates, must be identifiable.

As indicated above under question 6.2, it is prohibited to advertise prescription medicines to the general public. It follows that it is also prohibited to promote prescription medicines via **social media**, such as Facebook, Twitter, etc.

Compliance with these rules is being controlled in the same way as compliance with the general rules on pharmaceutical advertising.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

There are no specific rules concerning the required website security for advertisements directed at healthcare professionals. A company should take all security means to prevent access by the general public to a website that contains prescription-only medicinal products. Lack of adequate measures will constitute a violation of article 9 LMP.

For instance, it is a common practice that pharmaceutical companies make certain parts of their website only accessible to healthcare professionals if they log in with their RIZIV/INAMI-number.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

There are no specific advertising rules on links to and from websites. The acceptability of such links should therefore be assessed using the general principles applicable to pharmaceutical advertising.

Under normal circumstances, linking to independent websites is permissible as long as the inclusion of said link is not intended to circumvent the rules on pharmaceutical advertising (e.g., by referring to a website that clearly contains promotional content on the company's drug products). As the content of such independent website can change over time, pharma companies are generally advised to include a clear disclaimer that the information on the linked webpage is outside its control and responsibility.

A company is not responsible for reverse linking undertaken by an independent party.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

In case the website is accessible to the general public, it may contain the following information:

(i) general information regarding the pharmaceutical company itself, such as the size of the company, its organisation and history, its working area and a general list of specialties;

(ii) advertising of OTC drugs, to the extent in line with the applicable restrictions;

(iii) information on a specific pathology, on the condition that such information is complete and objective. If a treatment is being mentioned, all available treatments must be mentioned per therapeutic class, without brand names; and

(iv) if the website contains a summary of the company's specialties and refers to patient information or scientific leaflets of these products, those leaflets should be the official leaflets approved by the government.

Finally, as regards the **mandatory information** to be included in the advertising of medicinal products to the general public (see section 6), the FAMHP has issued specific guidelines for internet advertising.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no specific rules concerning the use of social media by companies in Belgium.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

The most significant development has been the enactment of the Sunshine Act, which, has entered into force on 23 June 2017 (see question 7.3).

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No significant developments in the field of pharmaceutical advertising are expected in the next year. The most recent significant development was the entry into force of the Sunshine Act on 23 June 2017, following which all companies within the pharmaceutical sector are now bound by transparency obligations and healthcare professionals will no longer be able to refuse the disclosure of transfers of values based on legal restrictions (e.g., data privacy). The Sunshine Act was for the first time applicable on premiums and benefits granted in the calendar year 2017. At the end of June 2018, these premiums and benefits were made public for the first time on the betransparent.be platform.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

We are noticing an increasing interest in patient support programmes financed by the pharmaceutical industry, both from the pharmaceutical industry itself and the government (as a means of limiting the healthcare budget). The Ministry of Health, FAMHP and pharma.be are currently still drafting a set of guidelines concerning these specific patient support programmes and their compatibility with the Belgian regulatory and compliance framework (advertising and inducement, data privacy, pharmacovigilance, etc.).

Furthermore, the "Implant Files", a global investigation on implants which have been poorly tested or which haven't even been tested at all, have created increased public and media awareness of the fact that certain premiums and benefits to healthcare professionals and donations to healthcare organisations could be abused to enhance or maintain a certain prescription behaviour. It is possible that the authorities will increase their scrutiny in this respect.

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Olivier's initial expertise in the Life Sciences sector was mainly transactional. His transactional expertise covers the entire life cycle of a drug product (R&D, clinical trials, supply chain and technical operations, commercial distribution), including M&A, product divestments and licensing deals (both early stage and established brands).

Since 2013, Olivier supervises Quinz's expert panel on healthcare compliance, which mainly tackles questions on the promotion of drug products and medical devices, on interactions with HCPs/HCOs, on patient support programmes, and on the use (and commercialisation) of healthcare data.

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Nele regularly provides regulatory support on questions related to the commercial launch of drug products. Recent assignments include advice in respect of (marketing) authorisation procedures (both in Belgium and before the EMA) and on pricing and reimbursement issues (in Belgium).

QUINZ ADVOCATEN AVOCATS ATTORNEYS

Quinz is a Brussels-based law firm with a strong focus on Life Sciences. Quinz assists the global, regional (EMEA, LATAM, APAC) and local (Belgian, Luxembourg and the Netherlands) legal departments of pharmaceutical companies on a broad array of (strategic, operational, licensing and M&A) transactions throughout the life cycle of a life sciences product. Quinz has also developed a sound expertise in regional and local regulatory work (including pricing and reimbursement, clinical trials, data transparency, marketing authorisation procedures, cGMP) and compliance matters (including transfers of value, promotion of drug products, antitrust compliance questions, patient directed programmes).

Quinz was founded in 2011. Its Life Sciences department is headed by Pieter Wyckmans and Olivier Van Obberghen.

Clients: Janssen Pharmaceutica; UCB; Bayer; Shire; Boehringer Ingelheim; Abbvie; and Roche.

# Brazil

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The manufacturing, distribution, marketing, import and export of medicinal products in Brazil are mainly regulated by the National Sanitary Surveillance Agency – ANVISA, the "Regulatory Agency".

The Federal Constitution sets forth in paragraph 4 of article 220 that the advertising of pharmaceuticals, as well as of other products that may interfere with public health, may be subject to legal and regulatory restrictions. There is a constant ongoing discussion, mainly in relation to non-prescription products, on the regulatory agency's (ANVISA) authority limits to impose regulatory advertising restrictions, independent from the enactment of a specific law authorising it.

That said, the advertising and promotion of medicinal products in Brazil is regulated, essentially, by the following legal instruments:

**Laws and Decrees**:

- 6.360/76 – regulates the Sanitary Surveillance to which medicinal products, their ingredients, medical products, cosmetics and cleaning products are subject. The implementation of this law is regulated by Decree 08.077/2013.
- 6.437/77 – defines violations of the federal sanitary legislation and establishes the corresponding penalties.
- 8.078/90 – the Consumer Protection Code.
- 9.294/96 – imposing restrictions on the advertising of medicinal products, products for smoking, alcoholic beverages, therapies and crop protection products. The implementation of this law is regulated by Decree 2.018/96.
- 9.782/99 – sets forth its statutory competence of the Regulatory Agency – ANVISA. The implementation of this law is regulated by Attachment I of Decree 3.029/99.
- Decree 8.077/2013 – regulates Law 6.360/76.

**Resolutions and other Acts of ANVISA**:

- RDC 096/2008 (as amended by RDC 023/2009) – regulates advertising and promotional actions in all their forms and media. Some concepts are defined in Normative Instruction ANVISA 5/2009.
- RDC 060/2009 – regulates free samples.
- Ordinance 344/98, issued by the Ministry of Health before ANVISA was created, remains in force and imposes specific restrictions on the advertising/promotion of medicinal products containing substances under special control (narcoleptics, anorexigenic drugs, antiretroviral drugs, immunosuppressant drugs, and others).

**Resolutions of the Federal Council of Medicine – CFM**:

- 2.023/2013 – Medical Professional Code of Ethics.
- 1.939/2010 – prohibits the interference of doctors in medicinal products campaigns such as "patient loyalty campaigns".
- 1.974/2011 – sets forth criteria for the participation of members of the medical profession in the promotion and advertising of any products or services related to the medical profession.

**Other Regulations**:

- The National Code of Self-Regulation in Advertising – sets forth a series of basic rules to be followed by all advertisers and media – CONAR.
- Codes of Conduct of class associations such as INTERFARMA (Brazilian Association of Research-Based Pharmaceutical Industries) and ABIMIP (Brazilian Association of Manufacturers of Non-Prescription Drugs).

### 1.2 How is "advertising" defined?

ANVISA defines the advertising/publicity of pharmaceutical products as the "array of information and persuasion techniques and activities with the objective of publicising knowledge, making more widely known or object of prestige a determined product or trademark, aiming to influence the public by means of actions intended to promote and/or induce the prescription, dispensing, purchasing and use of a medicinal product".

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no legal requirements covering this issue. Some companies do create "review boards" for promotional material. In general, these review boards are composed by members from the following departments: legal; compliance; medical affairs; and regulatory affairs.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

There are no SOPs required by law or regulation in relation to advertising or promotional activities. Companies are free to establish them according to their own policies. Companies are also free to not have SOPs related to promotional activities.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

No. However, RDC 096/98 determines that the organisers of scientific events at which the advertising and promotion of medicinal products will take place, must inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will be invited to the event.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Yes, they do. The ANVISA department that holds the authority for supervising and judging advertising/promotional violations is located under the General Management in charge of Sanitary Inspection and Supervision – GGFIS.

As regulated by RDC 096/98, the authorities also have the power to request that a corrective statement be issued and published.

Alleged violators have the right to appeal from decisions that consider certain promotions/advertisements have breached the applicable regulations and/or a decision to request a corrective statement. Such appeals will be judged by the ANVISA Board of Directors. Any final administrative decision may be reviewed by the Judiciary if the regulated entity/individual believes the administrative decision does not conform to the law.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Applicable penalties are listed in article 2 of Law 6.347/77 and range from warnings and suspension of sales, to the prohibition of advertising and corrective statements, as mentioned in question 1.6 above. These penalties may be accompanied by a fine that can vary from two thousand Reais to one-and-a-half million Reais, depending on whether the failure was considered by the authorities as "light", "serious" or "very serious".

Enforcement of these rules is the responsibility of the ANVISA and it is fairly strict. Due to the size of the country and the market, enforcement usually results from complaints and/or denunciations made by competitors.

Although this is not common, competitors do take direct action through the courts, but when they do, the complaints usually involve unfair competition and/or violation of intellectual property rights. These direct actions are most frequently taken within industry associations such as INTERFARMA or ABIMIP.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

ANVISA's enforcement of advertising regulations bears no direct or indirect link to any self-regulatory process or body, be it the National Code of Self-Regulation in Advertising – CONAR, or a Class Association Code like INTERFARMA, where, as a rule, the decisions are not made public. Competent authorities will investigate only matters that may constitute a breach of the law and the regulations they issue but may use the decision of any of the mentioned self-regulatory bodies to support their decision.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Other actions that can be taken would be, as a general rule, related to violations of (1) the Industrial Property Law – Law 9.279/96, that are considered acts of unfair competition as a result, for example, the unauthorised use of a trademark and/or a trade dress, imitation advertising signs and/or expressions, or (2) the Copyright Law – Law 9.610/98, as a result, for example, of using competitors' sales presentations, manuals, training material, etc. The action can be brought by the owner of the violated industrial property right or copyright or by a licensee if the Licence Agreement so permits. These actions will be filed as claims for civil indemnification and/or as a criminal law suit, as the case may be.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Although Brazilian pharmaceutical legislation and ancillary regulations strictly prohibit the advertising of medicinal products that are not registered by ANVISA, any such product may be discussed at scientific

events (congresses, symposia, etc.), whether the event is sponsored by the company responsible for the product or not. These discussions should be restricted to technical information like important findings in ongoing clinical studies, for example, and should not use product trademarks to avoid being perceived as an inducement to prescribe.

Note that while it is prohibited to produce, distribute and market medicinal products that are not yet registered by ANVISA, it is possible for an individual to import non-registered products for his/her own use under a specific prescription from a medical doctor duly registered to practise medicine in Brazil.

The same rules apply to off-label information and for these types of discussions; in this case, too, it is advisable not to use the trademark of the product, but instead just the name of the active ingredient.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Information on unauthorised medicinal products and/or off-label information can only be published as scientific information. In this case, using trademarks should be avoided. The INTERFARMA Code of Conduct expressly says that information on unregistered, off-label indications on products may only be used when related to medical and scientific information at congresses, symposiums or other scientific events, and provided that the audience is duly and previously informed that the product has not yet been registered and, as such, is not available in the market or that the indication is off-label.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Yes, but as mentioned above, only strictly as scientific information, and it is advisable to avoid the mention of trademarks.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Yes, provided the information is part of a strictly scientific publication. Although a previous request from the healthcare professional is not required under the legislation or ANVISA's regulations, the INTERFARMA Code of Conduct states that this type of information, as a rule, can only be sent if requested by the professional.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

It has not. The European Court of Justice judgments are not applicable in Brazil.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

As publicising unauthorised medicinal products is prohibited and only scientific information is allowed, information on unauthorised medicines or indications can only be sent to healthcare professionals. Also, such action could be interpreted as a violation of RDC 096/98, for potentially creating an expectation of sales.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Yes. Companies can hire healthcare professionals to render any reasonable professional services. A contract should be issued clearly delimiting the services to be provided.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

This is regulated under RDC 096/98. The required information in advertising to healthcare professionals is:

- (1) Brand name; (2) name of the active ingredient as it appears in the Common Brazilian Denomination – DCB; (3) ANVISA product registration number; (4) indications; (5) counter-indications; (6) warnings related to adverse reactions and interaction with other substances; (7) dosage; (8) prescription and dispensing classification; and (9) date of printing.
- In case the promotional piece on a prescription drug highlights the benefits of the product, the piece must also highlight at least one counter-indication and one frequent drug interaction.
- For vaccines, the advertisement must inform of the necessary number of doses for the complete immunisation.

Products containing substances under special control, as defined in Ordinance 344/98 mentioned above, are subject to further regulation.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Clinical Studies not included in the SmPC may be used as reference in advertisements to healthcare professionals. However, they must have been published in scientific publications, preferably with high evidence levels, and should be kept on file and made available to healthcare professionals and/or the authorities upon request.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Healthcare professionals cannot endorse medicinal products in promotional materials. In fact, the Federal Council of Medicine, through Resolution 1.974/2011, forbids medical doctors to

"participate in advertising of companies or products associated with medicine". Some participation is allowed for other professionals like dentists, pharmacists and nurses.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Although no specific number of studies or quantity of data is required, any such comparison must be based on studies that have been published, preferably with high evidence levels, and must include the complete bibliographical information.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

RDC 096/98 sets forth the rules for comparative advertising and unauthorised products or indications can never be mentioned in advertising.

Any price comparison is only allowed between interchangeable products, as defined in the law (Reference Products X Generics). However, if the products are not interchangeable, the comparison piece can only be handed to prescribing professionals and can only be made between products that have the same active ingredient and must be based on the cost of the treatment.

Comparative advertising of medicinal products is regulated, as mentioned above, by RDC 096/98 of ANVISA. Comparative advertising, in general, is regulated by several different pieces of legislation (Industrial Property; Code of Ethics or the Advertising Profession; and the National Code of Self-Regulation in Advertising) and there is an ongoing discussion on whether it is possible to use third-party brands in comparative advertising without their permission. Any decision to do so must be carefully evaluated.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Scientific papers may only be distributed to healthcare professionals. As mentioned above, promoters/sponsors of medical events, which include congresses, must inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will participate in the event.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Yes, as there are no regulations directly related to this matter. If the teaser relates to prescription products, they can only be made to prescribing professionals and/or published in scientific media.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

As a rule, pharmaceutical products in Brazil may only be promoted for the indications that are expressly included in the product's registration package and, therefore in the SmPC. Due to the strict regulations, in order to promote any product, even if in combination with another product, it would be necessary to include this "combined use indication" in the products' SmPC.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes, except for non-prescription products, biological products and products prepared in compounding pharmacies, in which case the provision of free samples is not allowed. The procedures and restrictions are clearly regulated in RDC 096/98 and RDC 060/2009. Products containing substances under special control, e.g. narcoleptics, are subject to additional regulations.

In general terms, the content of a free sample package must be 50% of the original, except for: products for chronic diseases (continuous use) and contraceptives, which must have the same content of the registered original; and antibiotics, which must have a complete treatment for one patient. Free sample packages must clearly and indelibly include the expression "free sample".

Free samples can only be distributed in ambulatories, hospitals, medical doctors' and dentists' offices, and the respective prescribing professional must sign a document indicating receipt of the samples.

As per articles 11 and 12 of RDC 060/2009, owners of the product registration must keep on file, for a minimum of two years after each lot's expiration date, all documents related to the production, distribution and pharmacovigilance data of the free samples and must send to ANVISA, annually, information on the production and distribution of free samples.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Only gifts of nominal value can be given to practitioners and they must be "institutional"; that is, they cannot be related to any specific product. Some class associations like, for instance, INTERFARMA, also require that the gifts: (1) be related to the medical practice excluding office supplies; (2) are of a symbolic value (around 50 dollars); and (3) are limited to three per year per doctor.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Yes. However, these gifts or donations must be institutional and cannot be linked to the requirement that the recipient institute promotes/advertises or standardises the use of any medicinal product. Information leaflets and/or annual reports on corporate responsibility published by companies to inform of their respective activities in that field cannot be used as advertising vehicles for medicinal products or even mention such products.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

There is no specific regulation with direct and clear wording on this. However, throughout the applicable legislation and ancillary regulations it is made very clear that no promotional action towards prescribing professionals can be (or be understood as) an exchange for prescriptions of any product.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Yes. The purchase and sale of medicinal products in Brazil operates on a standard international market basis, and so volume is one of the variables that may impact prices. Regulations strictly related to advertising do not make reference to this matter.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

No, as this is understood by health authorities as a violation of, among other rules, article 5 of RDC 096/98, which prohibits companies from granting benefits or advantages to prescribing and dispensing professionals, or anyone exercising activities related to the sale of medicinal products to the consumer.

In relation to specific benefits to patients, in a specific case six or seven years ago, and with the argument above, ANVISA denied the request of a pharmaceutical company that had consulted ANVISA on the possibility to pay for a certain lab test as it would be the only way to determine whether or not patients suffering from a determined illness could benefit from the use of the medication, as it would only work for certain subtypes of viruses. With the growth of availability of biological products this has become a little more flexible but there is need to examine the situation on a case-by-case basis.

The provision of administration apparatus or training linked to the supply of a particular medicine would be acceptable, but it should be apparent that these are necessary to insure, as much as possible, the correct use of the product.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

The National Code of Self-Regulation in Advertising strictly prohibits this type of scheme in relation to non-prescription medications.

In relation to medication sold under prescription, some medical institutions argue that parts of Law-Decree 4.113/42 (dating back to February of 1942) are still in force, including article five/XII, which sets forth that it is prohibited to advertise medicinal products with promises of reward (refunds) for the patients that do not have satisfactory results with their use. This piece of legislation is consistent with the prohibition of refund schemes in relation to non-prescription products.

Although such a scheme has been implemented a couple of times in Brazil, in at least one case the programme was terminated early, as the company decided to settle with one medical professional institution and does not discuss whether or not the Law-Decree mentioned above would still be in force.

It is important to point out, also, that Resolution 1.939/2010, issued by the Federal Council of Medicine, prohibits the participation of doctors in any promotion related to medicinal products, including the filling out of any form or document related to any type of discount to patients.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes. There is a specific chapter relating this matter in RDC 096/98. The three basic general rules for sponsoring continuing medical education are: (1) that the sponsoring is clearly not an exchange of prescription or participation of the sponsored doctors in promotional campaign; (2) it being the case, it must be very clear to participants of medical events which company/ies are sponsoring the event; and (3) a speaker in any such event who has relations with pharmaceutical companies or has any financial interest in them (e.g. a shareholder), must clearly inform this potential interest to the event organisers and this must be clearly indicated in the programme and at the start of his/her presentation, as well as in the annals of the event if applicable.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

There are no anti-bribery/anti-corruption legislation or regulations specifically applicable to the interaction between pharmaceutical companies and healthcare professionals/organisations, or to the pharmaceutical industry in general.

Bribery and Corruption, in Brazil, is the object of: (1) Federal Law 10.467/2002 that amended the Brazilian Penal Code; and (2) Federal Law 12.846/2013 that penalises actions against national or foreign public administration.

Anti-bribery/anti-corruption authorities will only investigate breaches in advertising to the extent that the breach configures an action of corruption or bribery.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

This is regulated by the same RDC 096/98, although there is no direct or specific regulation with a direct mention to hospitality. The INTERFARMA Code of Conduct, on the other hand, does indicate that locations of primarily touristic appeal are not permitted. No approval from the local affiliate is required. There is no specific threshold applicable, but it must be interpreted as not excessive or inappropriate for a healthcare event.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The generic answer is yes. Again, the most restrictive rules are set forth in the INTERFARMA Code, which limits payment only to those doctors who render legitimate services that are provided by that professional under a previous contractual obligation; in other words, payment or any type of remuneration, direct or indirect, for the time invested in the participation cannot be given to participants. Also, payments for travel, accommodation, food, etc., are limited to the participant and cannot be extended to family members or other invitees of the doctor.

Paying for the healthcare professional's time is not possible, as a rule. However, in some circumstances, there are exceptions. This would be the case for a specific closed company meeting of Advisory Boards, for which, however, participants must have written contracts specifying their services.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

There are no regulations directly related to this matter.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes. Any legitimate services, not in exchange for prescriptions and/or publicity, which are provided by doctors, can be paid to the healthcare professional. It is highly advisable that such services are covered in as much detail as possible in a written contract.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes. See the answer to question 5.4 above.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes. See the answer to question 5.4 above.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, this type of product can be advertised to the general public in all types of media and the limitations are regulated by RDC 096/98.

Advertisement of medicinal products to the public must always include the following generic warnings: (1) "If the symptoms persist consult with a doctor"; and (2) the generic phrase: "This is a Medicinal Product and its use involves risks. Consult with a Doctor and a Pharmacist. Read the insert/leaflet", which must be included, unless a specific warning related to a specific active ingredient is required by health authorities.

The following restrictions also apply to the advertising of non-prescription medicinal products:

(1) there can be no use of expressions such as "shown in clinical studies" or "scientifically proven";

(2) the advertising piece cannot suggest that the product would make healthy habits and visits to doctors unnecessary;

(3) there can be no use of celebrities to say that they make use of the product;

(4) the piece cannot use language that relates the product with an excessive intake of alcohol or food;

(5) there shall be no language relating the use of the product with physical, intellectual, emotional or sexual performance or to a person's beauty, except if the product has these specific properties approved by the regulatory agency – ANVISA;

(6) the piece cannot present in an abusive, frightening or misleading way visual representations of changes in the human body caused by illnesses or lesions; and

(7) the piece cannot include messages, symbols or images of any nature directed to children or teenagers.

The following restrictions apply to advertising any medicinal product, even if only to prescribing professionals:

The piece cannot:

(1) foster the indiscriminate use of medicinal products;

(2) suggest or stimulate diagnosis; and/or

(3) suggest that a medicinal product is tasty, yummy or delicious.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Advertising of prescription-only medicines to the general public is strictly prohibited.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Yes, disease awareness campaigns are allowed, including by private industry. In fact, Brazilian health authorities implement several campaigns each year especially related to vaccines, AIDS, hepatitis, flu and tropical diseases. In any disease awareness campaign, however, it is prohibited to mention any medicinal product. The campaigns should simply provide an incentive to the population to look to healthcare professionals for diagnosis or to go to health clinics (private or public) for a vaccination.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Yes, this is possible. Although there is no specific legal instrument related to this issue, in some cases the authorities have argued that some releases (or articles published in lay media) were in fact "advertising". It is advisable, whenever possible, that press releases to lay media, even in cases where the product is already registered, avoid the use of the trademark in favour of the name of the active ingredient. A legal review of the terms of the release is highly recommended.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

No restrictions apply. However, as the material will be distributed to the public, it should not have the form of advertising and should not serve as an inducement to the consumption of any medicinal product.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

As a general rule, this is permitted, and no requirements need to be followed. INTERFARMA, however, does address the issue and requires that the industry should never interfere with or influence the administration of the organisation and prohibits an industry from being the sole contributor to any organisation.

It is also important to point out that health authorities have been looking very closely at this issue, as some health authorities believe that, in some cases, donations are being made to patient support groups to pay for legal fees and expenses necessary for patients to sue the government to receive treatment (medicines or medical treatment) not yet available or registered in Brazil or that are very expensive and not included in government formularies.

Over the recent past, the São Paulo State Police and the São Paulo State General Attorney's Office has gone as far as to carry out investigations to verify whether three pharmaceutical companies were making donations that were directed to financing patient associations' legal costs for filing lawsuits as mentioned above. These investigations ended without finding hard evidence on the alleged financing of patient associations but there are at least some three or four still ongoing.

The judicialisation of health is a big issue in Brazil.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

As a rule, providing advantages or benefits to patients in relation to in-market products is not allowed by the Brazilian regulations, as set forth in article 5 of Resolution ANVISA RDC 096/2008. The exceptions would be to: (1) the items/services provided for patients participating in Clinical Trials, in which case these items/benefits should be described in the Clinical Trial Contract and in the Informed Consent Form; and (2) the apparatus and training mentioned in question 4.6.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Clinical trials in Brazil are regulated by Resolution CNS 466/2013. The disclosure of information on ongoing and/or complete trials is made, as a rule, only to the health authorities and to the respective Ethics Councils through partial and final reports prepared by the Head Investigator. There is no self-regulatory code in Brazil related to clinical trials.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Not as a rule. Resolution RDC 096/2008, however, requires that the sponsorship by companies of events, symposia, congresses, etc., must be informed to all participants.

There is no obligation to disclose the amount of sponsorship. Also, speakers at events, symposia, congresses, etc., if they are sponsored by any company, must disclose such, at the start of their presentation and in the records of the events, if they exist.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Not as a rule. The INTERFARMA Code of Conduct, however,

requires that speakers at events, symposia, congresses, etc., if they are sponsored by any company, must disclose this information. There is no obligation to disclose the amount of the sponsorship.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

As mentioned above, there is no obligation to disclose the amount of the sponsorship.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

The same legislation and regulations that apply to the advertising of medicinal products in Brazil in other media, also apply to advertising on the internet. So, should any company have sites that carry the advertising of medicinal products, they must follow these rules, including the need to ensure that advertising of prescription products can only be accessed by prescribing professionals.

RDC 096/98 has some regulations that are specific to internet advertising, setting forth, for example, how warnings have to appear (even indicating the type of font or requiring the use of bold fonts and capital letters in some specific cases).

ANVISA monitors health-related sites (pharmaceutical companies, pharmacies, distributors, clinics, etc.). Control of the content of internet sites is difficult as there are many and they contain a lot of information. Although some cases do exist, it is not common to see violation notices or fines applied for non-compliance.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

There is no specific requirement related to access security. The most common is that sites/pages intended for healthcare professionals must be accessed by the use of log-ins and passwords, and log-ins are usually the doctors' or dentists' registration number in their respective professional association, which some companies will check to verify if they are correct.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

In principle, the rules are the same; that is, there may be no advertising of prescription products to the general public. Although no specific rules regulate this matter, it would be advisable, as much as possible, to avoid the inclusion of links that will give access to the advertising of prescription products to the public in general. For obvious reasons, links to sites that advertise medicinal products that do not follow the rules will be understood and argued by ANVISA as being included on the site with the intention to try to avoid the legislation.

The most common occurrence of such cases is that companies will include generic disclaimers related to links, in which they state that they are not responsible for the content of links including comments, references, opinions, photos, advice, etc.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

A website may contain basically anything that the company finds suitable or necessary, except for advertising/promotional material related to prescription products.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no specific regulations controlling the use of social media by life sciences-related companies, or any other company for that matter. The use of social media by companies is regulated by the same legal instruments that apply to other media in relation to promotion and advertising. That said, on April 23, 2014, Law 12.965 was enacted, which sets forth the specific principles, rules and regulations on the guarantees, rights and obligations of internet service providers and users.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

There have been no changes in 2018 to the pharmaceutical advertising regulations.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

No. However, a review of Resolution RDC 098/2008 is scheduled to occur as the Office of The Attorney General has issued, some two years ago, an opinion indicating that some of the restrictions included in the Resolution have gone beyond the Agency's constitutional powers and, in some cases, especially in relation to non-prescription drugs, the industry has been successful in getting injunctive relief to suspend the enforceability of some of the rules.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

No, there are no general practice or enforcement trends that have become apparent in Brazil in 2018.

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# Bulgaria

Roman Stoyanov

Penkov, Markov and Partners

Yura Mincheva

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Advertising of medical products is regulated in the Medicinal Products in Human Medicine Act (MPHMA) and Ordinance No 1 of the Ministry of Health dated 25.01.2012 on the Requirements for Advertising of Medical Products ("Ordinance No 1"). In addition, the provisions of the Protection of Competition Act (PCA) and the Consumer Protection Act (CPA) have to be observed.

Applicable to a significant part of the industry is the Code of Ethics adopted by the "Association of the Research-Based Pharmaceutical Manufacturers in Bulgaria" (ARPharM). The observance of this Code is controlled by the Ethics Commission at ARPharM. The Code, reflecting the requirements of Council Directive 2001/83/EC, enhances the role of voluntary control of advertising and promotion to healthcare professionals of prescription medicinal products, as well as regarding the interactions of the pharmaceutical industry with the healthcare professionals, by self-regulatory bodies and recourse to such bodies when complaints arise.

Furthermore, ARPharM has adopted the "Code for Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Health Organizations" which is also applicable for the companies' organisation members.

The ARPharM members are obliged to observe along with the regulations of the Bulgarian legislation in place and the legislative norms of the European Union legislation, also the EFPIA Code on the promotion of medicines and the IFPMA Code on pharmaceutical marketing practices.

### 1.2 How is "advertising" defined?

The MPHMA defines the advertising of medical products as "any form of information, presentation, promotion or proposals with the aim of encouraging the prescription, sale or use of medicinal products" and includes: advertisement intended for the general public; advertisement intended for medical specialists; visits by medical sales representatives to medical specialists; the provision of sample medicinal products; sponsorship of promotional meetings; and scientific congresses attended by medical specialists, including the coverage of their travel and accommodation in the respective country in which the event takes place.

Excluded from this definition are the following: text appearing on the outer packaging approved during the licensing procedure for use; correspondence concerning a specific issue or problems pertaining to a particular medicinal product; information and instructions with regard to changes in packaging, warnings about adverse reactions as part of general measures for the safety of a medicinal product, trade catalogues and pricelists, provided they do not include data of advertising nature with regard to the medicinal product concerned; statements concerning human health or diseases when they do not, directly or indirectly, suggest a course of treatment, the prevention or diagnosis involving the use of medicinal products; and campaigns conducted by the Ministry of Health for the vaccination of the population, if material associated with them contains no data about a particular medicinal product.

According to the ARPharM Code of Ethics, promotion and advertising includes any activity undertaken, organised or sponsored by a pharmaceutical company, or performed with its authority and on its behalf, which promotes the prescription, supply, sale, application or consumption of its medicinal product(s).

A key principle of the Code is that any statement or message connected with the advertising and promotion of pharmaceuticals should be compliant with the Summary of product characteristics (SmPC) approved in Bulgaria. The Code of ARPharM is intended to guarantee that the pharmaceutical companies carry out their promotional and advertising activity, as well as their interactions with the healthcare professionals, in a truthful manner and in accordance with the high ethical and moral principles and values.

Furthermore, the Code defines "advertising" as all methods of promotion and advertising including, but not limited to: oral and written promotional activity and communications in periodicals; direct e-mail advertising; the activity of medical sales representatives; internet and other electronic communications; the use of audio-visual systems such as films, video recordings and data storage services; as well as the provision of samples, items of medical utility, information and education materials and hospitality.

The Code excludes from the definition of advertising the following activities: labelling on the package and the accompanying leaflet or usage guidelines, approved during the procedure of granting marketing authorisation; correspondence, accompanied by material of a non-promotional nature, prepared in response to a specific question related to a particular medicinal product; informative announcements and instructions referring to modifications of the package, adverse reactions warnings as part of the general precaution measures, commercial catalogues and price lists, provided that they do not include information of a promotional nature with respect to the medicinal product; statements, relating to human health or human diseases, provided they do not directly or

indirectly mention administration of medicinal products; activities related solely to non-prescription medicinal products; and non-promotional, general information about the companies (such as information directed towards investors or current/prospective employees), including financial data, descriptions of research and development programmes and discussions of regulatory drafts affecting the company and its products.

**1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?**

Pharmaceutical companies are obligated to set up a scientific unit for the distribution of information about the medicinal products for which they have been granted a marketing authorisation.

Under the Code of Ethics, every company must establish a scientific service (unit) in charge of the information about its medicinal products and the approval and supervision of non-interventional studies. The scientific service must include a medical doctor or a pharmacist who will be responsible for approving any promotional material before release. Such person must certify in an appropriate manner that he/she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the applicable codes and the applicable Bulgarian laws and regulations, that is consistent with the SPC and is a fair and truthful presentation of the facts about the promoted medicinal products. The scientific service must include a medical doctor or a pharmacist, who will be responsible for the oversight of any non-interventional study (including the review of any responsibilities assumed by medical sales representatives and other company/third-party contracted employees relating to such studies). Such person must certify that he/she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the Applicable Codes and the applicable Bulgarian laws and regulations.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

Though the legislation does not explicitly require SOPs governing advertising activities to be in place, it still provides that the medical sales representatives must have been trained through arrangements made by the MA Holder who has appointed them.

Companies in cooperation with ARPharM are obliged to continuously provide training and education to their medical sales representatives. The latter may use only promotional or advertising materials prepared in compliance with the provisions of the Code of Ethics and to be acquainted with the provisions of the Code of Ethics, the provisions of the effective Bulgarian legislation with regard to the advertising and promotion of medicinal products, to be adequately trained and to be well versed as to enable them to provide the healthcare professionals with correct and complete information on the medicinal products which they promote. This also applies to persons employed by third parties who perform the functions of medical sales representatives, as well as to all company personnel, who are not medical representatives, but promote and/or advertise medicinal products to healthcare professionals. Each company which agreed to comply with the Code of Ethics must have available at least one trained employee responsible for supervising the company and its subsidiaries to ensure that the standards of the Code are met. All company personnel, and any personnel retained by way of contract with the third parties, who are concerned with the preparation or approval of the promotional material or activities must be fully conversant with the requirements of the Codes of ARPharM, EFPIA, IFPMA and the relevant Bulgarian laws and regulations.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

The advertising of medicinal products to the general public has to be approved in advance by the regulator, the Bulgarian Drug Agency (BDA), as a general rule. Advertisement designated for healthcare professionals should only be notified to the regulator.

Advertising of medicinal products to the general public may be allowed only in respect of medicinal products, not subject to medical prescription. The procedure for approval of advertisement to the general public is initiated by an application, as per the standard model approved by the Executive Director of BDA, accompanied with: the project being advertised; notarised power of attorney issued by the MA Holder, if the application is filed by another person (proxy); literary sources of quotations, tables or other material used, if any; and a document for a paid fee. Advertisement projects must be clear, with a text, if any, that is easy to understand and allowing evaluating all of its elements: text and illustrations. Within a month following submission, the BDA's Executive Director shall authorise the advertisement or issue a motivated refusal. The refusal could be appealed.

In case within the month following the submission of the application for approval of advertisement the Executive Director does not issue an explicit order, the advertisement is considered tacitly approved.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The Executive Director of BDA has a right to stop, by virtue of an explicit order, the further publication of an advertisement, if it is considered to be a breach of law. Said order may also oblige the advertiser to publish or distribute, in coordination with the BDA, a corrective statement through the same means and in the same format and volume, as the very advertisement. The order may be appealed under the general regime for appeal of administrative acts, i.e. before the first instance administrative courts, which decisions could be appealed before the Supreme Administrative Court.

Issuing of an advertisement in breach of ARPharM's Code of Ethics does not entitle the BDA to stop it. Still, the Code provides the right not only to the members of ARPharM, but also to individuals, to file a complaint before the Ethics Commission (of ARPharM). The Commission may also act *ex officio* in such events. The decisions of the Ethics Commission are appealable before an extended panel of the latter. The Commission may also insist on the issue of a corrective statement, which should be coordinated with it.

Advertisements could infringe the provisions of the PCA for unfair competition. The Bulgarian Commission for Protection of Competition (CPC) is empowered to take preliminary measures and to suspend the public broadcast of such advertisements until it conducts a compliance investigation and if it finds a violation of the

PCA, it has the right to order immediate ceases for further publication of such advertisements. The CPC may, notwithstanding the pecuniary sanctions for an infringement, order the advertiser and/or the advertising agency to publicise at its expense and in a suitable manner, the decision of the CPC establishing the infringement, as well as a respective corrected advertisement. The orders and the decisions of the CPC are appealable before the Administrative Court – Sofia District and the decision of the latter before the Supreme Administrative Court.

In addition, advertisements could be subject to analysis under the Consumer Protection Act (CPA) for unfair or misleading commercial practices.

When the Commission for Consumer Protection establishes that the advertisement is unfair commercial practice, the Chairperson of the Commission could issue an order prohibiting the application of such commercial practice and/or could fine the advertiser.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Breaches of MPHMA are sanctioned with an administrative fine of up to BGN 20,000 (approximately EUR 10,228).

The Ministry of Health heads the state control of medicinal products. Immediate direction is performed by the Chief State Health Inspector, by the Chairperson of the National Council on Prices and Reimbursement of Medicinal Products, by the BDA's Executive Director and by the Regional Health Inspectorate Directors, who are state inspectors controlling medicinal products.

Every person may submit a complaint before the Ethics Commission at ARPharM. The Ethics Commission may on its own initiative commence proceedings against a company for violations of the Code. If a violation is established, the Commission may impose a sanction of up to BGN 7,000 (approximately EUR 3,579) and in double amount in the event of a repeat violation, disseminate its decision amongst all members of ARPharM, inform the parent-company of the breaching entity and even suggest to the Managing Board an exclusion of the violating member from ARPharM.

The competitors could report the breaches to the competent authorities.

Infringements of the prohibitions for unfair competition are subject to an administrative fine of up to 8% of the net turnover of the company for the last financial year. Some actions were undertaken against pharmaceutical companies for unfair competition before the CPC. Usually the CPC will acts on complaints or alerts made by competitors.

Under the CPA, the infringers could be fined for unfair commercial practices with a fine ranging from BGN 1,000 up to BGN 30,000.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

In general, the decisions or other measures of self-regulatory bodies do not have an immediate legal impact on the potential actions of the competent authorities. The authorities can investigate matters already assessed by self-regulatory bodies to the extent that they constitute a violation of the law. Matters constituting a breach of a code shall, and typically are, investigated by the relevant branch organisation.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The competitors could file a claim for unfair competition before the CPC and could request a ban of the advertisement. The decision of the CPC in which it establishes a violation of the Protection of Competition Act is binding for the civil courts, before which all affected competitors could claim indemnification of the damages incurred from unfair competition, where the violation could not be proven by the claimants.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

The MPHMA explicitly provides that advertising is allowed only for medicinal products for which an MA has been issued. Information articles or audio-visual media, information brochures and posters used at scientific meetings and other events for scientific purposes, shall comply with the latest approved summary of the product characteristics (SPC). Also, the promotion and advertisement must encourage reasonable use of the medicinal product by presenting it objectively and without any exaggeration of its properties. The statements should not suggest that a given medicinal product or active substance have any special merits, qualities or characteristics, unless this could be substantiated.

MPHMA and Ordinance No 1 do not contain any specific provisions for the exchange of information or discussion of information between healthcare professionals about unauthorised medicine. As a rule, these are non-compliant with Bulgarian law and thus not allowed. The same generally applies with respect to off-label use, though in practice the regime is more liberal. Still, in our view, dissemination of information and/or discussions about the medicine before that product is authorised could be made at scientific meetings in an instance where no specific name of product is mentioned, but only its API and general data regarding the trials with such API. If the product is still authorised in some other country, the mentioning of the product (trade) name could be also possible.

The same considerations are also valid as regards off-label information about a certain product, provided, however, that the scientific event's main topic is not focused on such off-label use or information, respectively, the provided off-label information should not exceed the merits of the question. Disclosing off-label information to the general public is considered a violation.

In addition, a company could in theory disclose factual information about an unauthorised medicinal product in response to unsolicited inquiries by a healthcare professional. This would rather be considered disclosing information regarding a producer of medicine (company) and should not be considered as advertising.

Moreover, the Ethics Code prohibits the promotion or advertisement of a medicinal product or a therapeutic indication of a particular medicinal product prior to the grant of the marketing authorisation. However, this prohibition is not intended to restrain the rights of the scientific community and of the general public to be comprehensively informed about the progress of science and medicine. It is also not intended to restrain the full and accurate exchange of scientific information with respect to a particular medicinal product, including the disclosure of the appropriate scientific facts in specialised or general communications media and at scientific conferences.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Such information, if it is beyond the scope of the MA and if it is used for advertising purposes, may not be published. However, off-label information concerning a specific issue or problems intended for healthcare professionals should not be considered as promotion. Publications in scientific journals which comply with the above should be permissible.

The disclosure of scientific facts in specialised journals should also not be considered a violation.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

There are no specific rules in Bulgarian law in this respect. We deem that, in general, issuing press releases about unauthorised medicines could be possible only as regards scientific factual information, if the name of the product is not mentioned. The message to the mainstream public media should be anonymised as much as possible.

In addition, it should also be permissible to offer statements concerning human health or diseases when they do not, directly or indirectly, suggest a course of treatment, or the prevention or diagnosis involving the use of such medicinal products. Disclosing information regarding the financial status of a company (if this includes information about unauthorised medicines and/or off-label information) is permissible, unless, of course, it is made with the aim to advertise. Reporting to shareholders and others about information related to a specific medicinal product should be made in compliance with the requirements of the law.

Providing information about the progress of science and medicine should not be considered a violation of the general prohibition for advertising unauthorised medicines.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Correspondence concerning a specific issue or problem, if it includes such information, should not be considered advertising. Again, any information of the type may be sent without mentioning a particular medicinal product's name, API or other distinctive feature and the product should not be easily deductible from the provided information. If the company discloses such information in the merits of a promotion campaign, it would most likely be considered as information of a promotional nature.

Nonetheless, sending such information about an unauthorised product directly to healthcare professionals may be considered to be disguised promotion and advertising.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The MPHMA was amended in accordance with Regulation (EC) 726/2004. When a certain disease treatment has no alternative in Bulgaria, medicinal products authorised in European Union Member States but not authorised in Bulgaria, may be administered to individual patients. Each year, the Minister of Health approves a Drug List acting upon a proposal by in-patient care establishments and following the opinion of the relevant Expert Council in the specialist area of the disease.

In addition, medicinal products which are authorised in another country, and not an EU Member State, could be prescribed by special expert committees.

The supply of such products is arranged directly by the medical institution where the treatment is held and through wholesalers of medicinal products or international organisations, but not through pharmacies. Thus, making price lists for products available to pharmacists without an MA, either for named-patients, compassionate use or other purposes, is forbidden.

In addition, MPHMA entitles the Minister of Health, based on the motivated proposal of the Chief State Health Inspector, in coordination with the Executive Director of the BDA, to allow by virtue of explicit order for a specified period of treatment, the use of a medicinal product which has not been authorised, in the event where an epidemic has been declared in the country, caused by pathogenic microorganisms or toxins, or an alleged or confirmed spread of chemical agents or nuclear radiation exist and there is no suitable medicinal product allowed for use (in line with Article 5 of the Directive). However, no specific procedure as to the distribution of such products is regulated.

Moreover, no marketing authorisation is required for medicinal products for modern therapy, prepared for a specific patient following an individual physician's prescription in accordance with specific quality standards, and administered in a medical institution at the exceptional professional responsibility of the physician.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

There is no explicit regulation on this question in Bulgarian law. Given the broad scope of the definition for "advertising", in our view, the provision of such information to institutions would be considered as promotional activity as regards unauthorised medicines, and thus forbidden.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

No specific pharmaceutical law governing this topic exists. Healthcare professionals may be involved in market research exercises relating to such marketing materials if it is ensured that their involvement is not misused in order to indirectly promote an unauthorised product.

Under the Ethics Code, contracts between companies and healthcare professionals or medical societies for providing healthcare services are only allowed if the services in question are provided to enhance healthcare or scientific research; and do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Furthermore, the Code provides that when hiring a professional for market research, there should be a written contract which specifies the nature of the services to be provided and the basis for payment of those services. The consultancy services must fulfil all the following criteria: a legitimate need for the services has been clearly identified by the company in advance of requesting the services and entering into arrangements with the prospective professionals; the criteria for selecting professionals are directly related to the identified need and the persons responsible for selecting the professionals have the qualification necessary to evaluate whether the particular healthcare professionals meet those criteria; the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need; and the contracting company maintains records concerning and makes appropriate use of the services provided by the professionals.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The content of advertisement must correspond to data in the SmPC approved in the course of the MA and shall present only indications specified in the course of the MA. The advertisement of a medicinal product must only suggest its correct use, objectively presenting its therapeutic indications, without exaggerating the possibilities for treatment, prevention or diagnosis using the medicinal product concerned. The advertisement may not contain an offer and/or promise of a gift and/or another material or nonmaterial benefit.

Under the Ethics Code, each promotional and advertising material, including advertisements in specialised medical issues, must be accompanied by the SmPC or by information consistent with the data available in the SmPC, specifying the date of its latest approval by the BDA. When the purpose of the advertisement is only to serve as a reminder about a well-known medicinal product, this requirement is waived, provided that the advertisement includes no more than the trade name of the medicinal product, the international non-proprietary name of the active substance, the name of the company or a picture of the package. The advertisement, serving as a reminder, must not contain any promotional claims.

Moreover, the Code provides that promotion and advertising must be accurate, balanced, fair, objective and sufficiently complete in order to give an opportunity for the recipient to form his/her own opinion about the therapeutic value of the medicinal product. The information in promotional and advertising materials must be based on up-to-date analyses of data, substantiated by scientifically valid evidence, and must not mislead or create the wrong impression. The additional information and scientific evidence confirming the statements laid out in the promotion or advertisement must be provided by the company by a request from the healthcare professionals. The data, quoted in promotional materials or advertisements, including publications in specialised issues, must be provided to the persons that have required it within a month as of the receipt of this request. Promotion and advertisement must encourage a reasonable use of the medicinal product by presenting it objectively and without exaggeration of its properties. The statements should not suggest that a given medicinal product or active substance has any special merits, qualities or characteristics, unless this could be substantiated. When the promotion and advertisement refer to any published studies, they must be clearly indicated with the respective cross-reference.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

The advertisement must not contain misleading information. Information not included in the SmPC about consistent studies made upon the scientific standards could appear in the advertisement. It is not permissible to mention contradictory studies or studies regarding off-label indications.

The Ethics Code of ARPharM provides that promotion and advertisements should be directed only to those healthcare professionals for whom it could be reasonably assumed that the information contained is of interest to them.

The word "safe" shall never be used without proper qualification in order to describe a medicinal product. The word "new" should not be used to describe any medicinal product, presentation or therapeutic indication that has been available in the Bulgarian pharmaceutical market for more than one year from the date of placing it on the market.

Promotion and advertisements should not contain claims that the product has no adverse effects, toxic hazards or risk of addiction or dependency. Promotion and advertisements should not resemble messages or designs used by other manufacturers in a manner which might be misleading or lead to confusion.

The companies' members of ARPharM conducting the promotion and advertising or interaction with the healthcare professionals bear the responsibility for their actions and for the content of the promotional and advertising materials which is expected to be accurate, objective and in compliance with the SmPC, as well as with the published scientific information. The company bears the responsibility for the activity of its employees and third parties conducting the promotion and advertising of its medicinal products or interaction with healthcare professionals. The activity of the employees and the third parties, representing the companies on promotion and advertising of their medicinal products or on the interaction with healthcare professionals, shall not breach the provisions of the Ethics Code. This responsibility is not limited only to the medicinal product subject to promotional activity, but also to the information provided or to the statements made with respect to other medicinal products that should also be in line with the SmPC, regardless of the information/statement source.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

An advertisement must not contain recommendations by healthcare professionals. It is not allowed to present information which refers to recommendations from scientists, medical professionals or other individuals who, due to their popularity, could encourage the use of the medicinal product. Furthermore, a medical specialist or a person claiming to be a medical specialist may not engage in direct or indirect advertising of medicinal products in the printed and/or electronic media, as well as on the Internet.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

In general, any comparative claims should observe the provisions of the PCA, as noted below in question 3.5. Under ARPharM's Ethics Code, any comparative claims should be based on up-to-date analyses, which are scientifically proven, and do not mislead or present untrue information. In view of this, using data for "head to head" clinical trials would be recommendable.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

As a general rule, comparative advertising is permitted by the PCA when: it is not misleading and is not an unfair commercial practice under the meaning of Art. 68e, 68f and 68g of the PCA; it compares goods or services satisfying the same needs or intended for the same purpose; it objectively compares one or more features of the goods and services which are substantial, comparable and representative for these goods and services, including their prices; it does not lead to confusion between the advertiser and his competitors or between trademarks, trade names, other distinguishing marks, goods or services of the advertiser and those of his competitors; it does not discredit or denigrate the trademarks, trade names, other distinguishing marks, goods, services, activities or situation of the competitors; it compares goods with the same designation of origin; it does not take unfair advantage of the reputation of the trademark, trade name or other distinguishing marks of the competitors or of the designation of origin of the competing goods; it does not present the goods or services as imitations or replicas of goods or services bearing a protected trademark or trade name.

Similar dispositions for comparative advertising are implemented in the Protection of Customers Act.

The Ethics Code provides that promotion and advertisements should not resemble messages or designs used by other manufacturers in a manner which might lead to misleading or confusion. The Code also prohibits comparative advertising if: it specifies the medicinal products that have different therapeutic indications in comparison with the medicinal product, subject to the promotion or advertising; or if the advertisement does not objectively clarify one or several of the main, relevant properties and peculiarities of the medicinal products concerned; or if the information creates confusion with respect to the company conducting the promotion and advertising and its competitors, or with respect to the medicinal products subject to this promotion and advertising, as well as to the medicinal products used to serve as a comparison, or regarding the trademarks of the medicinal products specified. The advertisement would contradict the Code if it contains statements defining the medicinal products used for comparison as "imitation or copy" of the medicinal product, which is subject to the promotion or advertising; or if it contains disparaging or disgraceful statements concerning the products, activity, personal or business standing of a company competitor or its employees; or it contains the trade name of the competitive medicinal product or the name of the company competitor.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no specific rules in the Bulgarian legislation. However, scientific papers regarding authorised medicinal products may be distributed to healthcare professionals on scientific meetings, conferences, etc. Under the Ethics Code of ARPharM information, educational materials may be provided to healthcare professionals if they are not high in value and they are directly relevant to the professionals' practice in a way that will improve patient care. The distribution of such materials should not represent an incentive for the healthcare professional to recommend or prescribe the medicinal products mentioned in the papers.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Bulgarian law does not regulate "teaser" advertisements. This type of advertising should be permissible if it complies with the general principles and rules governing the advertising of medicinal products. In general, such teaser should contain the minimum required information for advertising a medicinal product (name of product/name of the company, etc.) and should not be misleading. If the teaser advertisements are used to increase the curiosity of the public, and do not present the minimum of information required for advertising medicinal products, they will be considered misleading, and thus inappropriate.

According to the law and the ARPharM's Ethics Code, when the purpose of the advertisement is only to remind healthcare professionals about a well-known medicinal product, the advertisement should include no more than the trade name of the medicinal product, the international non-proprietary name of the active substance, the name of the company or a picture of the package. The advertisement, serving as a reminder, must not contain any promotional claims.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Under the MPHMA, the content of the advertisement must

correspond to data from the SmPC approved in the course of the marketing authorisation and shall present only indications specified in the course of the marketing authorisation.

With regard to the general rules of advertising, it would be recommendable for the MA holder for Product B to firstly amend Product's B SmPC, in order to promote the combination with Product A.

However, if the information is not misleading and is intended only for healthcare professionals and has been approved in Product A's SmPC, it could be used in contacts and discussions with the healthcare professionals. Still, to the extent that the combination of the two products shall invoke an off-label use indication of Product B for Product A's indication, in our view, direct advertisements would be a contradiction to the Bulgarian laws.

The legislation, as well as the Ethics Code foresees that promotional and advertising materials have to be accurate, objective and complied with the SmPC, as well as with the published scientific information. The companies bear responsibility for information provided or to the statements made with respect to other medicinal products that should also be in line with the SmPC, regardless of the information/statement source.

## 4 Gifts and Financial Incentives

### 4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Bulgarian laws allow the healthcare professionals to be provided with gifts that have no more than two samples of the same pharmaceutical form of the medicinal product in one calendar year. The sample must be no larger than the smallest package allowed for use and placed on the market for this product and every sample must contain the sign "sample" on the package.

Under the Ethics Code, samples of medicinal products can, by exception, be given to a healthcare professional who is authorised to prescribe the medicinal product in his/her practice, in order to acquaint the healthcare professional with the medicinal product. Only samples from new products can be provided.

A healthcare professional cannot be provided samples of the medicinal product as an incentive to recommend, prescribe, sell or use this product in his/her practice. Samples of medicinal products containing psychotropic or narcotic substances subject to control under the Law for Control of Narcotic Substances and Precursors, shall not be provided. Samples of medicinal products shall be given only in response to a written request by the healthcare professional who is authorised to prescribe this medicine. The written request must be signed and dated and completed by the healthcare professional requesting the sample.

### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

The MPHMA explicitly provides that when medicinal products are presented to medical specialists, the medical sales representatives may not offer gifts or any other material or nonmaterial benefits.

The Professional Ethics Code of Doctors in Bulgaria also proclaim as inadmissible any forms of agreements between representatives of pharmaceutical companies and doctors for the dispensing of medicines and consumables with the aim of gaining any materials or other benefits.

The member-companies of ARPharM are bound not to perform or encourage activities directed towards the inducement of healthcare professionals to prescribe particular pharmaceuticals for material benefits (items, money and services). Items, subsidies, financial support, scholarships, grants and invitations to participate in conferences should not be offered or provided to healthcare professionals against the prescription or undertaking of engagement to prescribe definite medicinal products.

Still, the Ethics Code allows the provision of information and educational materials to healthcare professionals, if: they are not high in value; they are directly relevant to medical practice or pharmacy; and providing them will improve patient care. Their provision is not an incentive for the healthcare professional to recommend, prescribe, supply, sell or administer a specific medicinal product. Information and educational materials with a value not higher than BGN 40 (approximately EUR 20), and items of medical utility only, aimed at educating healthcare professionals or providing patient care which cost up to BGN 100 (approximately EUR 50) are permissible. These items may be supplied with the aim of supporting the healthcare professionals' activity and to overcome the consequences of the insufficient public funding for healthcare in the country. The items provided must not be part of the necessary/mandatory equipment for the medical practice and may include medical and scientific literature.

### 4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

There are no explicit provisions in Bulgarian law in this respect. Still, the legislation admits donations of money to medical treatment facilities (hospitals), which the tax laws recognise as expense donations made to hospitals. In this respect, gifts or donations of money would be possible, if they do not serve to encourage the distribution of the medicinal products of the company. Generally, it should be ensured that all donations have a non-profit purpose. These criteria are met when donations are made to non-profit organisations that in their turn support healthcare organisations.

The above considerations are valid also with regard to the donation of equipment, or funding the cost of medical or technical services. Donations and gifts are also possible when they serve for educational or training purposes, research or support of the healthcare system.

Under the ARPharM's Ethics Code grants, pecuniary or in kind, for healthcare organisations and medical societies who carry out healthcare and/or scientific research may be provided by a company only if they are in support of healthcare and scientific research and they are documented and the documents are stored by the donor and could be disclosed upon request by the Executive Director of the Association, by another company or by the ARPharM's Ethics Committee. They are permissible if they do not represent an incentive to purchase, supply, dispense or administer medicinal products. Donations in the form of repair work, technical equipment and furniture may be provided only to hospitals for inpatient care, outpatient and diagnostic consultative centres. Donations of medicines may be provided only to hospitals for inpatient care. Grants to healthcare professionals – physical persons, are not allowed.

In addition, the Code provides that the companies are allowed to provide items of medical utility, which cost up to BGN 100 (approximately EUR 50), if they are not part of the mandatory

equipment and have educational purpose. Such items should be beneficial to enhancing the provision of medical services and patient care.

Donations of medical and scientific literature should also be permissible. Still, they should not be in high value.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Providing educational materials or items of medical utility that could lead to changes in prescribing patterns is prohibited as a general rule. It is only permissible to provide educational services to the extent that they do not influence the prescribing of the medicinal products of the company. Furthermore, educational goods and services should not be high in value. The provided benefits should be relevant to the medicinal or pharmaceutical practice and should be given to the healthcare professionals in connection with their work.

Moreover, contracts between companies and healthcare organisations or medical societies for providing healthcare services are only allowed if the services in question are provided by the company's organisation to enhance healthcare or scientific research; and do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Art. 29 of the PCA generally prohibits any action when carrying out economic activity, which is contrary to good faith commercial practices and damages or may damage the interests of competitors. The good faith commercial practices are defined as the rules determining the market behaviour resulting from the laws and the ordinary commercial relations and not infringing good morals. Thus, providing materials that could lead to changes in prescribing patterns as prohibited by the law (as described above) would represent prohibited unfair completion.

In addition, companies should comply with the applicable codes in the selection and sponsorship of healthcare professionals to participate in training and events.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

There are no explicit regulations in Bulgarian law in this respect. Still, it is not prohibited, but would very much depend on whether rebates are offered for prescription medicinal products and especially whether for reimbursable products by the National Health Insurance Fund. In the latter case, though not explicitly prohibited, the rebates would contradict the aim and spirit of the reimbursement rules.

The general competition protection rules should be observed, as well. Under the PCA, the sale of significant quantities of goods over an extended period of time at prices lower than the costs of their production and marketing, with the purpose to unfairly solicit clients, is prohibited.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

No, to the extent such offer would influence the unbiased assessment of the healthcare professionals in prescribing medicinal products.

It could also violate the provisions of the PCA where the offering or granting as a supplement to goods sold or services provided, either free of charge or at an ostensible price, of other goods or services is prohibited. Exception is made for: i) advertising items of minor value and bearing a clear indication of the advertising undertaking; ii) items or services, which according to commercial usage, are an attribute to the goods sold or services provided; and iii) goods or services as a rebate for sales in higher quantities shall be prohibited.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Such refund schemes are not explicitly prohibited by the Bulgarian legislation but are in contradiction with the spirit and the purpose of the law. Generally, reimbursement is made by the National Council on Prices and Reimbursement of Medicinal Products, established with the Ministry of Health. Offering a refund scheme would be in violation of the Regulation on prices of medicinal products for the reimbursable products.

The promotion of a refund scheme for over-the-counter medicine or prescription-only medicine (non-reimbursable) may be considered as misleading advertising, especially if it involves a statement about the efficiency of the product, which is prohibited.

The offering of a refund scheme of the type might also be considered as violating the general competition protection rules.

Moreover, the Bulgarian legislation prohibits any type of advertising which creates the impression that the benefits of the use of the medicinal products are guaranteed or the use of the product is not linked to any side effects. Advertisement which creates the impression that a certain medicinal product is better than another is considered unlawful.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

There is no explicit regulation in the legislation on this matter. Pharmaceutical companies may sponsor continuing medicinal education through scientific events organised in compliance with the respective regulations. Under the ARPharM's Ethics Code, companies should comply with the applicable codes for good practice. Any grants must be documented and disclosed. If the sponsorship includes gifts, advantages and any kind of benefit which are linked to the change of patterns of prescribing or supplying a medicinal product by a physician, it would constitute a violation.

Organising trainings and events related to scientific and educational training by a company is permitted, and the rules of the ARPharM's Ethics Code should be observed.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Under the Bulgarian Criminal Code, there is broad prohibition for bribery. Currently, there are both state and self-regulating bodies that adopt rules and internal policies in order to ensure that the relationship, between the pharma companies and the healthcare professionals are transparent. The interactions between them are not well established due to the various approaches of the anti-bribery authorities and the healthcare organisations.

There is no relationship between the authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions in the country. Still, the authorities could collaborate with one another, on occasion and when needed.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Member companies of ARPharM, when in the process of deciding whether to sponsor an event, to participate in an event or to sponsor healthcare professionals to participate in an event, should consult the database for a preliminarily estimate of such an event, with the database available on the website of ARPharM.

When conducting promotional meetings, scientific congresses, symposia, or other scientific events attended by healthcare professionals, sponsors or organisers may bear the costs of healthcare professionals on their travel, stay, and registration fees in the country in which the event is taking place. The expenses must be strictly limited to the professional and scientific purposes of the event and to persons who are medical specialists.

Under the Ethics Code, hospitality, in which the participants in the event are accommodated in extravagant and luxurious hotels, is considered inappropriate. Extravagant and luxurious hotels are all 5-star hotels, located in resort destinations. Hospitality offered in connection with promotional, professional or other scientific events, shall be limited to travel, meals, accommodation and registration fees. The cost of a single offering of food and beverages to a healthcare professional cannot exceed the equivalent of BGN 100 (approximately EUR 50). All forms of hospitality extended to healthcare professionals must be reasonable and be strictly limited to the main purpose of the event. "Reasonable level" of hospitality provided as a rule means that it must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

Events, organised in the territory of Bulgaria, should not have a duration of above three 24-hour periods. Not less than six hours of each full day of the event shall be arranged for working/scientific programme. International events organised by a company should not continue for more than four 24-hour periods. Not less than six hours of each full day of the event shall be arranged for the working/scientific programme. This provision shall not be applied to events organised by the main office of the company. The maximum permissible limits for hospitality are: flight tickets (to Bulgaria and international) – economy class. Business class is allowed only with the exception of a non-stop flight with over six hours duration. Stay in a hotel – hospitality is limited to the value of an accommodation and breakfast package. All additional expenses are on the account of the participant.

Outside the territory of Bulgaria, the monetary threshold set in the country where the event takes place (i.e. the "host country") shall prevail. In the case of sponsorship of healthcare professionals to participate in an international event, the provisions of the national code of the country where the healthcare professional practices/exercises/activities shall apply.

No company may organise or sponsor an event held outside Bulgaria (international event) unless: most of the invitees come from other countries; and, due to logistical considerations, it would be better to hold the event in another country; or in view of the location of the respective source or expertise, which is the subject matter of the event, it would be logistically justified to hold the event in another country. An international event can be used for presenting and handing out to the participants promotional information on medicines, drugs or therapeutic indications, which are not authorised for use in the country, where the international event takes place, or these are registered under other conditions provided that (a) any such promotional materials specifically state that a medicinal product, formula or therapeutic indication is not authorised for use in the country and with explicit indication of the countries where the medicinal product, formula or therapeutic indication is permitted to use, and (b) any such promotional material, which contains information on prescriptions (indications, warnings, etc.), authorised in countries where the product is registered for use should include an explicit statement that authorisation conditions vary across countries.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Under the Ethics Code, a healthcare professional cannot be paid only for attending an event. It would be preferable to pay them if they are active participants (for instance speakers, moderators, members of committee, etc.) and not only for the time spent. Travel, accommodation and enrolment fees are by definition paid by the company that sends the healthcare professional to the event (as pointed out in question 5.1 above).

The amount of presentation/lecturer fees (for Bulgarian residents) is determined in correspondence with the significance of the event (of regional or national character), the academic status of the lecturer and the form and duration of the presentation. The fees shall not be

higher than one-and-a-half times the average salary for professionals employed in the sphere of healthcare and social services with a full-time employment contract, determined by the National Statistics Institute for non-academic persons, and two times the average salary amount for professionals employed in the sphere of healthcare and social services with an employment contract, for academic persons. The limits of the fees are calculated accordingly by the average salary for the country of those working in the healthcare sector.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

When organising events, the companies bear the responsibility for their actions and for the content of the promotional and advertising materials which are expected to be accurate, objective and complied with the SmPC, as well as with the published scientific information. The companies bear the responsibility for the activities of their employees and third parties conducting promotion and advertising of their medicinal products or interaction with healthcare professionals. The activity of the employees and the third parties, when they represent the companies in promotions and advertising events, shall not breach the provisions of the Ethics Code.

Still, a pharmaceutical company would not be held responsible for the hospitality arrangements and the content of independent meetings, if it is only responsible for providing a sponsorship for certain doctors to attend.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Generally, it is permitted to use healthcare professionals, on individual or in group practice, as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies or training services, participation at advisory board meetings, and participation in market research. The consultants can receive an appropriate remuneration for their services as well as a compensation for the expenses made during the execution of the contract obligations.

Healthcare professionals may be paid to provide expert services, such as participation in advisory and other boards. Contracts between companies and healthcare organisations or medical societies for providing healthcare services are only allowed if the services in question: are provided by the organisation to the company to enhance healthcare or scientific research; and do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

A legitimate need for the services has to be clearly identified by the company in advance of requesting the services and entering into arrangements with the prospective consultants. The contracts between the consultants and the companies should be in writing and should include provisions regarding the consultant's obligation to declare that he/she is a consultant to the company in any public appearance about a matter that is the subject of the agreement or any other issue relating to that company, and also provisions regarding the obligation of the healthcare professionals that are still practising their profession or employed by the company, to declare his/her employment arrangement with the company in any public appearance about a matter that is the subject of the employment or any other issue relating to that company.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

It is possible to involve healthcare professionals in post-marketing studies. When a non-interventional post-marketing safety study is conducted, the medical specialists cannot receive financial or other incentives for participation, except for compensations for the time and means spent.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Generally, it is acceptable to pay healthcare professionals to take part in market research involving promotional materials for medicinal products that have been granted an MA by the BDA. The payments should not encourage or depend on prescribing the advertised medicine. The research should aim at further improvement of the quality of the healthcare services. Under the ARPharM's Ethics Code in cases of healthcare professional answering questionnaires for market research such as one-off phone interviews or mail/email/internet questionnaires, the remuneration of the healthcare professional can be up to BGN 60 (approximately EUR 30).

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Non-prescription medicines may be advertised to the general public after an authorisation of advertisement by the BDA. The advertisement of the medicine must only suggest its correct use, and present objectively its therapeutic indications, without exaggerating the possibilities of the treatment, prevention or diagnosis using the medicinal product concerned. The content of the advertisement must correspond to data from the medicinal product summary approved in the course of the MA and shall present only indications specified in the course of the MA.

Quotations taken from medical or scientific literature must be faithfully reproduced, for the exception when adaptation or modification is required for the purposes of consistency with the applicable codes, in which case it must be clearly specified that the quotes have been adapted and/or modified, and the sources must be identified. Promotion and advertisements should not resemble messages or designs used by other manufacturers in a manner which might lead to misleading or confusion. The information in the advertising materials must be based on up-to-date analyses of data, substantiated by scientifically valid evidence, and must not mislead or create a wrong impression.

Promotion and advertisement must encourage reasonable use of the medicinal product. The statements should not suggest that a given medicinal product or active substance have any special merits, qualities or characteristics, unless this could be substantiated. When advertisement refers to any published studies, they must be clearly indicated with the respective cross-reference. The word "safe" shall

never be used without proper qualification in order to describe a medicinal product. The word "new" should not be used to describe any medicinal product, presentation or therapeutic indication that has been available in the Bulgarian pharmaceutical market. Promotion and advertising must not be disguised. They must be presented in a manner allowing them to be identified as advertising and promotion by their recipients.

The law prohibits advertisements for the general public which contain or in which: it is stated that the use of the medicinal product excludes the need for medical advice or surgical intervention (through diagnosis, suggestion of advice on postal care, etc.); it is suggested that the effects of the use of the medicinal product are guaranteed, and not accompanied by adverse drug reactions or are better or equivalent to those obtained from another treatment or use of another medicinal product; it is suggested that one's health can be improved by the use of the medicinal product; it is suggested that the non-use of the medicinal product can be harmful; the information is directed exclusively or mainly to the attention of children; the information refers to recommendations from scientists, medical professionals or other persons who, because of their popularity, could encourage the use of the medicinal product; it is suggested that the medicinal product is a food, cosmetic product or other commodity; it is stated that the safety or efficacy of the medicinal product is due to its natural origin; a description or a detailed description of a history of a disease is presented, leading to an inappropriate self-diagnosis; it is claimed that there is a healing effect by using incorrect, threatening or misleading expressions; misrepresenting, through threatening or misleading expressions; identifying specific diseases and symptoms such as tuberculosis, sexually transmitted diseases, other serious infectious diseases, oncological diseases, chronic insomnia, diabetes and other metabolic and endocrine diseases; and it is expressly stated that the medicinal product is authorised for use.

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

It is prohibited, in any way, to advertise prescription-only medicines to the general public. An exception is provided only for vaccination advertising campaigns, carried out by marketing authorisation holders, subject to the general requirements for authorising the advertisement of medicinal products.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Pharmaceutical companies are not allowed to make disease awareness campaigns. In Bulgaria, only the Ministry of Health conducts disease awareness campaigns and they are permitted only if the materials associated with them contain no data about a particular medicinal product. Furthermore, the presented data should not directly or indirectly suggest a specific medicinal product.

### 6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

In general, such statements could be regarded as unlawful advertisement and are thus prohibited.

Still, statements and releases concerning human health or diseases when they do not directly or indirectly suggest a course of treatment would be acceptable. Warnings about adverse reactions as part of general measures for the safety of a medicinal product are also permitted. It is possible to state the process of development of a medicinal product without mentioning its name and/or API. However, there is the possibility that such press releases will be viewed as disguised promotion and advertising, which are not permitted in the Bulgarian legislation, and thus any releases should be very carefully prepared.

It is prohibited to promote or advertise a medicinal product or a therapeutic indication of a particular medicinal product prior to the grant of a MA. This prohibition is not intended to impair the right of the scientific community and of the general public to be comprehensively informed about the progress of science and medicine. It is not intended to restrain the full and accurate exchange of scientific information with respect to a particular medicinal product, including the disclosure of appropriate scientific facts in specialised or general communications media and at scientific conferences. It also should not limit reporting to shareholders and others about information related to a specific medicinal product in compliance with requirements or recommendations of the law, the rules or regulations.

### 6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

The annual reports must be submitted to the Bulgarian Commercial Register and thus become public, just like any information kept in this register. Descriptions of products and research initiatives in such reports should be informative and it is highly unlikely to be perceived as an advertising attempt. The shareholders in the respective pharmaceutical company have the right to be informed about the company's development and the research it conducts. Furthermore, non-promotional, general information about the companies, such as information directed towards investors or current/prospective employees, including financial data, descriptions of research and development programmes and discussions of regulatory drafts affecting the company and its products, is not considered advertising. Thus, reporting to shareholders and others about information related to a specific medicinal product should be in compliance with requirements or recommendations of the law, the rules and the regulations.

### 6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

There is no specific regulation in Bulgarian law in this respect.

The matter is governed only by an industry code – Code of practice on relationships between the research – based on pharmaceutical industry and patient organisations in Bulgaria from the ARPharM. All events sponsored or organised by a company must be held in an appropriate venue that is conductive to the main purpose of the event. Hospitality extended in connection with events shall be limited to travel, meals, accommodation and registration fees. Hospitality may not impose conditions obliging patient organisations or their members to advertise or promote particular medicinal products.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

There is no prohibition in general for such activity. Explicitly prohibited is the provision of medicinal products to the general public. Still, under certain conditions it is admissible to donate medicinal products to named patients.

Items of insignificant value may be provided to or for the benefit of patients, if such items are directly related to the dispensing or use of the medicinal product. The competition protection rules should also be observed.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The BDA observes all published guidelines of the European Commission. The Agency applies the transparency rules adopted in the Regulation of the European Union (EU) on Clinical Trials No 536/2014.

The companies must disclose information regarding ongoing trials to the BDA and to the Ethics Committee for Clinical Trials with the Minister of Health, as part of the trial authorisation process. The sponsor has to notify the authorities about the termination of the trial and is also obliged to submit to the BDA and the respective ethics committee a final report on the clinical trial.

The sponsor is obliged to notify the BDA, the regulatory bodies of all Member States in which a trial takes place, in the case of a multi-centre trial, and the ethics committee, respectively, of any suspected unexpected serious adverse reaction that has occurred in the course of a clinical trial and has resulted in death or has proven to be life-threatening, within seven days at the latest of receiving the information about it.

Of course, any changes to the trial protocol, unless it is insignificant, should be notified to the BDA and the Ethics Committee, as well as prior authorisation sought by them.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no such obligation in the Bulgarian legislation.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

ARPharM has adopted a Code for Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Health Organizations. This code introduces the requirements of the Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA) to disclose transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations. The Code affects the companies which are members of ARPharM. In addition, companies that are not members of the association, but are members of EFPIA, whether directly or through a subsidiary, are obligated to comply with the code, including provisions governing the sanctions under the code.

Companies are obligated to annually disclose transfers of value, each reporting period covering a full calendar year. The first reporting period was the calendar year 2015. Disclosure shall be made on the website of the company, a link to which shall be published on the information website in Bulgarian http://transparencybg.org/, to which there is unrestricted and public access.

Transfers of value shall be disclosed on an individual basis. Each company shall disclose on an individual basis for each clearly identifiable recipient, the amounts attributable to the transfers of value to such recipient in each reporting period. Such transfers of value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to the relevant recipient. Companies must provide information on: grants and donations to healthcare organisations; contribution to costs related to events, such as registration fees, sponsorship agreements with healthcare organisations or with third parties appointed by a healthcare organisation to manage an event, travel and accommodation costs; and fees for service and consultancy.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

The companies which are affected by the Code are obliged to disclose such information. There is, however, the possibility to disclose information on a category-by-category basis.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Advertising prescription-only medicines is forbidden on the Internet. This rule is strictly applied. The advertisements for over-the-counter medicines on the Internet must comply with the legal provisions with regard to advertising in general and may be performed only by pharmacies or drug-stores, duly licensed under Bulgarian law.

Control over advertising on the Internet is exercised by the BDA or Regional Health Inspectorates. The imposition of penalties for internet advertising not in compliance with the legal requirements has been evidenced several times above.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

There are no specific legal requirements in the Bulgarian legislation for websites that concern only healthcare professionals. However, in order to comply with the general provisions for advertising prescription-only medicines, a statement should be made that the information is intended for professionals, or a question could be posed asking whether the user is a health professional or not. The company should establish a reasonable safe access system in this respect.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Usually, companies are responsible for all of the content published on their websites and, of course, the content must not contradict Bulgarian legislation in general. Furthermore, the content must not violate intellectual property rights. If the linked content violates third-party rights, the company is obliged to remove it. In addition, the company may also be held responsible for content which a third party may publish on the company's website via online portals such as forums, etc. The company may be obliged to remove offensive and inappropriate content.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Practically any company that owns a website must publish information disclosing its name, legal form, address, etc. The information should be truthful, sufficient and easily attainable. The general rules set in the Bulgarian legislation for advertising of medicinal products apply.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The rules mentioned above that regard the content published on the companies' websites are applicable to the content that the companies publish via social media. Personal data protection rules apply when the companies use social media to collect user data for the purposes of advertising.

The Council for Electronic Media in Bulgaria is the authority in charge of supervising the broadcasting legislation and it may impose sanctions when an administrative offence is established.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

As a general rule, the Bulgarian legislation and the self-regulatory bodies in the industry are impacted by the health policies of the European Union. The European Medicine Agency's guidelines also have their place in the development of the legislation. The Ministry of Health adopted a 2020 Strategy in 2015 which sets forth the policies and the priorities in the field for the next few years.

In the past few years, the efforts were focused on transparency issues concerning the implementation of The Code for Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Health Organizations adopted by ARPharM and reducing potential conflicts of interest.

The Medicinal Products in Human Medicine Act was amended with regard to Art. 83 of Regulation (EC) No 726/2004 of the European Parliament and of the Council. The new regulations allow treatment involving a medicinal product for compassionate use pursuant to Art. 83. When a disease treatment has no alternative in Bulgaria, medicinal products authorised in European Union Member States may be administered to individual patients. In addition, the Minister of Health approves a Drug List of these medicines.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

Currently, we are expecting new regulations on compassionate use. The Ministry of Health has prepared a project of an Act, which is still not submitted in the National Assembly.

The new rules shall detail the relationship between the pharmaceutical companies and the respective authorities. It is expected that programmes for compassionate use will be developed. It is expected that the costs related to the use of such medicinal products will be paid by the pharmaceutical companies, and not by the state. The Act envisages criteria, procedures, algorithms on the selection of patients, as well as the presentation of evidence for the product's safety.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

Progress has been made in the area of implementing and monitoring compliance with the EU regulations. As a tendency, this shall continue to improve. The BDA continues to be the most important authority that observes compliance with the respective legislation in the field.

Pharmaceutical companies are aware of the prohibitions for unfair competition and the considerable amounts of fines for their violations and thus follow competitor's advertising campaigns, in order to be able to act timely in case of competitor's incompliance which could harm their activity and impede effective competition.

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# Canada

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Two pieces of federal legislation, the *Food and Drugs Act* ("*FDA*") and *Controlled Drugs and Substances Act* ("*CDSA*"), provide the general framework for advertising medicinal products in Canada. Regulations made under those acts including the *Food and Drug Regulations* ("*FDR*"), the *Natural Health Products Regulations* ("*NHPR*"), the *Narcotic Control Regulations* ("*NCR*"), and the *Benzodiazepines and Other Targeted Substances Regulations* ("*BOTSR*") provide further details.

Generally speaking, advertisements must not be false, misleading, deceptive, or likely to create an erroneous impression regarding character, value, quantity, composition, merit or safety. Any advertisement must be in line with Health Canada's terms of market authorisation ("TMA") which can take the form of a Product Monograph for prescription drugs, or other product information document for non-prescription drugs and natural health products. Further restrictions apply depending on the classification of the product and the target audience of the advertisement. These are discussed more fully below.

The FDA also prohibits the advertising to the general public of any drug as a treatment or cure of any disease listed in Schedule A of that Act, which includes diseases considered to be sufficiently serious to warrant this prohibition such as cancer, diabetes, and hypertension.

In addition, Health Canada has published various guidance documents and advisories including a policy on *The Distinction Between Advertising and Other Activities* ("*Distinction Policy*") and a guidance document on *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)* ("*CAG's for non-Rx Drugs*").

Laws generally applicable to advertising including the federal Competition Act and provincial consumer protection acts also apply.

There are *Advertising Preclearance Agencies* ("*APAs*") in Canada, two of which have developed their own Codes. While preclearance is not legally mandated, these Codes are generally considered to be industry best practice and compliance is recommended. The two Codes are *The Pharmaceutical Advertising Advisory Board* ("*PAAB*") *Code of Advertising Acceptance* ("*PAAB Code*"), and *Advertising Standards Canada* ("*ASC*") *Canadian Code of Advertising Standards* ("*ASC Code*"). The *PAAB Code* applies principally to advertising to Health Care Professionals, while the *ASC Code* applies to direct-to-consumer ("DTC") advertising.

Manufacturers may also be members of industry organisations such as *Innovative Medicines Canada* ("*IMC*"), *The Canadian Generic Pharmaceutical Association* ("*CGPA*"), or BIOTECanada. These organisations have codes of conduct that apply to member companies and could impact advertising activities.

### 1.2 How is "advertising" defined?

Advertising is defined in the *FDA* broadly to include any representation by any means for the purpose of promoting directly or indirectly the sale or disposal of any drug. This definition is also reproduced in various regulations made under the *CDSA*.

To help distinguish between advertising and other activities, Health Canada has developed the *Distinction Policy*. The distinction between advertising and non-promotional activities is made based on the purpose of the message. Messages intended to promote drugs are advertising, while messages intended to provide information are generally not. If the primary purpose is not clear, or there is more than one purpose, Health Canada provides a list of considerations that will help determine if a message is advertising. These include the context, the audience, the message provider, the sponsor, the manufacturer's influence on the message, the content, and the frequency of delivery.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no legally mandated requirements; however, APAs may require sign-off to confirm that the advertisement is consistent with the TMA prior to their review.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no requirements for manufacturers, however, it is generally considered best practice to have SOPs in place to aid with compliance. APA's are required by Health Canada to have written policies, procedures, and standards for the review of advertising materials.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

The use of APAs in Canada is not mandatory but is encouraged by Health Canada. Certain industry organisations such as IMC require members to submit materials to the PAAB for preclearance, and failure to do so could result in a penalty. For DTC advertising, many magazines/media outlets require preclearance by ASC before they will accept an advertisement.

In many cases, advertising complaints are handled by the APAs. Submitting materials for approval prior to use reduces the risk of such complaints as well as the risk of findings of non-compliance if a complaint is made.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The PAAB has the authority under its Code to withdraw clearance and request suspension of publication. This decision may be appealed in accordance with the *PAAB Code*.

ASC has the authority under its Code to request that the advertiser appropriately amend or withdraw an advertisement that is found to be non-compliant following a complaint. If the advertiser refuses to comply, it can advise exhibiting media (e.g., the television station broadcasting an ad), publish the violation, and inform relevant regulatory authorities. The *ASC Code* outlines the appeal process.

Neither of these APAs have statutory authority to stop publication and rely on advertisers and publishers to comply voluntarily. If they are unable to obtain compliance they can forward the complaint to Health Canada.

If Health Canada determines that an advertisement is in breach of the law, it can request the advertiser to take appropriate corrective measures which can include discontinuation or correction of the advertisement. If it determines that the health risk is low, it will usually work cooperatively with the advertiser to ensure these actions are taken. If the health risk is high, it may seize the offending materials, issue public communications, or seek remedies from the courts such as injunctions.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Most enforcements follow a complaint, usually made to one of the APAs or directly to Health Canada. APAs can revoke clearance, request amendment or withdrawal, publish details of the offence (including the name of the advertiser), advise the publisher, or refer to Health Canada.

As discussed in question 1.6 above, Health Canada may request that the advertiser take appropriate remedies. However, the *FDA* also provides for penalties for non-compliance with that Act, including its advertising provisions. Non-compliance is punishable by up to two years' imprisonment and/or a fine of up to CAD $5 million. Knowingly making false or misleading statements to the Minister of Health or recklessly causing a serious risk of injury in contravening the *FDA* or its regulations can lead to a higher penalty or longer term of imprisonment. Other potential penalties include warnings, stop sale orders, seizure of products, suspension of market authorisation, injunctions, refusals of importation, and initiation of criminal proceedings. These penalties tend to be used for more serious matters, and we are not aware of any cases where they have been used in the context of advertising non-compliance.

Both IMC and CGPA have the ability to impose sanctions including monetary penalties and publication of the details of the offence for breaches of their respective Codes. The IMC Code incorporates the *PAAB Code* by reference, and member companies could therefore face a financial penalty for contravention of the *PAAB Code*.

The Competition Act also provides for penalties for false and misleading advertising, however, most enforcement will take place via an APA or under the *FDA*.

Competitors do not generally have a right of direct action through the courts without something more (e.g., defamation). Competitors may make complaints through the various avenues discussed above.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

Health Canada has the ultimate regulatory authority with respect to federal drug advertising laws. However, it supports and encourages the voluntary use of APAs to ensure adherence to federal legislative requirements. As the national regulatory authority, it establishes the TMA for the product, which provides limits within which that product can be advertised. It also develops policies and guidance documents that govern the interpretations of the legislation. Health Canada also oversees the enforcement of advertising prohibitions. It takes a risk-based approach to enforcement and strives to be transparent.

The APAs review and preclear advertisements to determine if, in their view, they are compliant with relevant legislation, Health Canada guidance and policies, and their respective Codes. APAs also adjudicate complaints, and Health Canada has stated that the first route for complaints is through APAs unless the complaint relates to DTC advertising of prescription or biologic drugs, or to unauthorised health products. These complaints should be submitted directly to Health Canada. Complaints that are referred to an APA can be referred to Health Canada by the APA if, in the APA's judgment, they contravene the legislation and either present an imminent and/or significant health risk or the APA is unable to achieve compliance from the advertiser.

APAs may seek clarifications from Health Canada, and in some circumstances, Health Canada can seek clarifications from APAs. APAs may assist in developing Health Canada Guidelines, and there is an annual bilateral meeting between APAs and Health Canada. The PAAB also has Health Canada representation on its board.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The *Competition Act* is federal legislation that prohibits: materially false or misleading advertising; misleading warranties or guarantees; representations of the performance, efficacy or length of life of a product that are not based on adequate and proper tests; misrepresentations about ordinary selling price; misleading use of testimonials; bait and switch selling; and double ticketing. Complaints can be made to the Competition Bureau. The Commissioner will investigate the complaint and decide whether to initiate proceedings which can be civil or criminal in nature.

The *Trademarks Act* prohibits the making of a false or misleading statement, tending to discredit the business, goods, or services of a competitor. It also prohibits passing off, creating confusion as to the origin of the goods, and making certain misleading statements about products. Any "interested person" may bring an application to the Federal Court.

Provinces also have consumer protection legislation that may address competition.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Advertising a drug prior to market authorisation is strictly prohibited by the *FDR*. Further, off-label advertising is considered to be contrary to the prohibition in the *FDA* against advertising that is false, misleading or deceptive, or likely to create an erroneous impression. APA Codes, as well as the *IMC Code*, also prohibit off-label advertising.

However, as discussed in question 1.2, not all communications will be considered advertising. Manufacturers may respond to unsolicited requests for information about off-label uses. Generally, this should be done by the medical affairs group rather than the sales force in order to ensure the communication remains informational rather than promotional. Manufacturers may also sponsor talks or conferences where off-label uses are discussed provided the manufacturer has no control over the agenda or content of any presentation. IMC members are also required to meet certain further obligations including requiring speakers to disclose the unapproved nature of any off-label use.

Communication for the purposes of recruiting for clinical trials is also allowed, provided certain requirements are met.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Information may be published provided it is not promotional in nature. Generally, this is limited to publication by someone other than the drug manufacturer, usually of clinical trial results, in scientific references such as peer reviewed journals.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Again, any such release must be non-promotional in order to be compliant with Canadian legislation. Information must be limited to the name of a drug, its proposed use, a statement that the drug is still under investigation, and a statement that it has not yet obtained market authorisation. Any public statements or statements to healthcare professionals would be considered advertising and therefore prohibited.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Information on unapproved indications can only be provided by companies in response to unsolicited requests from healthcare professionals. Any proactive promotion or solicitation of requests is prohibited.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

This judgment has not affected Canadian law. Making such information available would be considered to be advertising of an unapproved medication and therefore prohibited.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

According to the Distinction Policy, formulary kits may not be considered advertising if they are limited to that which would normally be required to support a formulary application. Formulary kits are defined as material prepared for review by pharmaceutics and therapeutics and formulary committees, on which a decision to include a drug product in a formulary may be based.

If they are disseminated, in whole or in part, to a wider audience simultaneously, or at a later date, it may be viewed as advertising.

Otherwise, the general prohibition applies and manufacturers may only respond to unsolicited requests for information.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Market research is generally not considered advertising and therefore not subject to the restrictions discussed above. However, care should be taken to ensure that such activities do not become promotional in nature.

The *IMC Code* provides requirements for member companies that help ensure this distinction is maintained. For example, market research should only be done for a legitimate purpose and not in a way that could be viewed as advertising. The number of participants should be limited to a reasonable number, and participants should not leave meetings with any materials. Market research should be separate from other activities and sales staff should not be present. While these are non-binding on companies who are not members of IMC, compliance will help ensure that marketing activities remain non-promotional. For a full list of restrictions and guidelines, the *IMC Code* should be consulted.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

The PAAB is the APA responsible for advertisements directed to healthcare professionals. The general legislative requirement is that an advertisement will not be false, misleading, deceptive or likely to create an erroneous impression. The *PAAB Code* provides details as to how that is achieved in promoting to healthcare professionals. The key requirements are:

- the indication verbatim from the Product Monograph must appear at least once in the advertisement;
- advertising must be accurate, complete and clear and designed to promote credibility and trust;
- the brand name, generic name, and Federal drug schedule (e.g., prescription medication, narcotic, controlled drug) must appear at least once in the advertising copy;
- advertising must be presented in a manner that accurately interprets valid and representative research findings;
- advertising must reflect an attitude of caution with respect to drug usage with emphasis on rational drug therapy and proper patient selection; and
- advertising should provide sufficient information to permit assessment of risk/benefit in a prominent manner. This is what the PAAB terms "fair balance". At a minimum, it includes information on how to locate the full prescribing information (Product Monograph); however, for certain advertisements more detail is required.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

In Canada, the SmPC is known as the TMA (specifically the Product Monograph for prescription products).

As set out above, advertisements must be in line with the TMA, and any use claims must be in line with the approved indication. It is possible to make other types of claims, provided they are supported by appropriate evidence, however, it is generally not appropriate to make off-label claims or reference studies that include off-label patients. An example of an acceptable claim is a place in therapy claim, which can be made provided it is supported by consensus guidelines. Claims comparing a drug to a competitor product should be supported by head-to-head trials, and pricing claims should be supported by independent pricing data.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Endorsements by healthcare professionals are generally not accepted. The PAAB requires appropriate evidence in support of any claims, and for most claims, an individual's opinion will not provide sufficient support.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There is no minimum number, but head-to-head trials are required to support comparative claims. Studies must be well designed, and generally must be published or accepted for publication in peer-reviewed journals before they can be relied on. Studies that were reviewed as part of a submission to Health Canada can also be relied on.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Health Canada's *Therapeutic Comparative Advertising: Directive and Guidance Document* provides guidelines on comparative advertisements. The following principles must be observed in advertising that compares therapeutic aspects of drugs:

- the compared drugs have an authorised indication for use in common, and the comparison is related to that use; or, in addition to the common indication for use, a second authorised indication is claimed as an added benefit of the advertised drug;
- the comparison is drawn between drugs under the same conditions of use in a similar population;
- the claim does not conflict with the TMA of the compared products;
- the claim is of clinical relevance in humans (i.e., relevant to treatment selection);
- the evidence generated to substantiate the claim is conclusive and based on a consideration of appropriately interpreted, scientifically robust data; and
- the claim and its presentation should identify the compared entities and the medicinal use related to the claim if not readily apparent, not obscure the therapeutic use of the advertised drug, not attack the compared drug in an unreasonable manner, and be expressed in a way that can be understood by the intended audience.

The *PAAB Code* provides details on the types of evidence and is generally considered acceptable, and also stipulates that advertisements must acknowledge competitors' trade marks.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

Distribution of scientific papers and proceedings of congresses is permitted.

As a matter of best practice, the reproduction should be provided unedited and in full, with no link between the text and promotion of a drug, unaccompanied by any additional information prepared for the purpose of promoting a drug, unmarked, without a summary, and without reference to the availability of a product. If any of these conditions are not met, the reproduction may be considered advertising and will need to comply with applicable advertising laws.

Any paper referencing an off-label use or an unauthorised drug should only be distributed in accordance with all criteria described above. Further, as discussed above in question 2.4, distribution of such materials should only occur pursuant to an unsolicited request.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There is no prohibition against "teaser" advertisements; however, they must comply with advertising regulations including the prohibition against advertising for unapproved uses. Even if an unapproved use is not explicit in a "teaser", it could be viewed as implicit and caution should be exercised.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Both products would have to be promoted in line with their respective product monographs. If, for Product A, the monograph states it must be used in combination with Product B for a particular indication, then that fact must be communicated. If the Product B monograph does not include the new indication, the holder of the MA cannot promote it for that use.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

The *FDR* allows the distribution of samples to registered and practising physicians, dentists, veterinary surgeons, or pharmacists. There is no ability to distribute to other types of healthcare professional. Samples for narcotics, controlled drugs, and drugs that have not yet received authorisation may not be distributed.

Samples must be distributed pursuant to a signed order indicating the name and quantity of drug requested and must be labelled in accordance with the regulations. The order may specify repeats at specified intervals for a period not exceeding six months. The person distributing samples to the healthcare professional must maintain certain records for a two-year period following the distribution.

The *IMC Code* provides further guidance to innovative manufacturers including a requirement that samples be included on an invoice and marked "Not for resale". Conversely, the *CGPA Code* prohibits generic manufacturers from providing samples.

Provincial regulations and rules governing healthcare professionals may also impact the ability to distribute samples.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

There is no legal prohibition, however, the *IMC Code* specifically prohibits them, and most healthcare regulatory bodies have rules and professional codes that either specifically prohibit accepting gifts, or prohibit professionals from entering into arrangements that could be perceived as conflicts of interest.

The *IMC Code* provides a narrow exception for "service-oriented items" which are items whose primary goal is to enhance the healthcare professional's understanding of a condition or its treatment or better perform their professional activities, although the value must not exceed CAD $150. Examples include textbooks or educational tools such as anatomical models.

The *CGPA Code* allows for gifts that are modest in nature and expense, and that comply with any applicable legislation.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Healthcare organisations are regulated provincially, and the rules may vary from province to province. Generally speaking, such funding is allowed provided there are no incentives to prescribe, recommend, purchase, supply or administer a product and that nothing is offered that would interfere with the independence of a healthcare professional's prescribing or dispensing practices.

Companies may also provide patient support programmes and funding for medical practice activities provided the objective is to better patient health outcomes. Funding should not be provided for day-to-day administrative or operational responsibilities. Benefits received by a healthcare professional must be incidental to the primary objective.

The *IMC Code* also allows for the loan of medical equipment to improve prevention, diagnosis, or treatment of diseases. Like other funding, care must be taken to ensure that it is not promotional. The Code sets out conditions to be complied with.

The *CGPA Code* allows for scholarships, bursaries, and endowments to be made.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The provision of medical or educational goods is generally allowed as discussed in question 4.2; however, distribution of such items must not be carried out for product promotional purposes.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

The rules relating to volume-related and other discounts vary from province to province. Generally, volume-related discounts to hospitals and other publicly funded health groups are permitted. Discounts to pharmacies are restricted in some provinces but not in others. Ontario is generally considered to be the most restrictive province in this regard, and these payments must comply with legislated provisions and may not exceed 10%.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

This is not permitted. Such services can be provided if they are unrestricted in nature. Likewise, patient support programmes can be offered provided the decision has already been made to prescribe a particular product. The programme must not be an inducement to prescribe.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

There are no federal laws or regulations prohibiting refunds for medications that do not work. Any publication or communication of a refund scheme may have to comply with advertising laws depending on the facts.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Pharmaceutical companies are permitted to sponsor continuing medical education subject to the restrictions in the *IMC Code* which include:

- topics must not be promotion-oriented and presentations must give a balanced view of all relevant treatment options;
- the presenter should disclose any financial or other material affiliations and acknowledgment of sponsorship should appear on all programme-related materials;
- full editorial control should reside with the presenters;
- remuneration of speakers and moderators should be at fair market value and travel/accommodation remuneration does not extend to spouses or other companions;
- remuneration of attendees is prohibited, although meals and refreshments are permitted within reason;
- manufacturers should not be involved in the development of or payment for entertainment; and
- sales representatives may attend, but may not detail a product (outside of a booth set up at a congress that is segregated from the learning programme).

In contrast with the fifth bullet above, the *CGPA Code* (applicable to generic manufacturers), allows for the payment for attendees to travel to conferences under certain conditions.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

There are no federal anti-bribery rules specific to interactions between pharmaceutical companies and healthcare professionals or organisations. The rules that are generally applicable (e.g., *Criminal Code* provisions) would apply. Provincial regulations may restrict the types of payments that can be made (e.g., many types of rebates are prohibited in Ontario).

The *IMC Code* and *CGPA Code* also provide ethical codes of practice that prohibit practices such as bribery. Any complaints made to IMC or CGPA or proceedings under their respective Codes would be unlikely to prevent investigation by provincial and federal authorities. In fact, the *CGPA Code* expressly states that the CGPA believes that the administration and enforcement of its Code should be the responsibility of the Agency charged with overseeing the drug programme in the relevant jurisdiction. It will therefore defer to provincial authorities where appropriate.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Hospitality payments are generally prohibited. There are limited exceptions, and in certain circumstances manufacturers may pay for such things as meals and travel expenses. These exceptions include:

- occasional reasonable meals/refreshments for attendees at meetings, educational events, or other conferences provided the meal is incidental to a genuine business or educational discussion;

- travel and accommodation for presenters or moderators at conferences, but not for their spouses or companions; and
- travel and accommodation for attendees at international conferences held outside of Canada subject to certain restrictions geared to ensuring that the conference serves a legitimate educational purpose.

As discussed in question 4.8 above, the *IMC Code* prohibits travel payments for attendees of conferences in Canada, while the *CGPA Code* allows it.

Both the *IMC Code* and the *CGPA Code* are silent on who should approve arrangements in cross-border situations. However, the *IMC Code* does require that members ensure that International Affiliates comply with that code.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

As discussed in questions 4.8 and 5.1 above, expenses and honoraria can be paid to speakers and other presenters at scientific meetings. The *IMC Code* prohibits such payments to attendees, while the *CGPA Code* allows payment of attendee travel expenses.

Further, healthcare professionals will have legal and ethical obligations of their own. Healthcare professionals are regulated provincially and are often subject to rules and codes of ethics. These may prevent them from accepting certain payments, under threat of misconduct proceedings.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

As discussed in previous questions, pharmaceutical companies are limited in the funding that they can provide. Further, IMC requires that editorial control of the content of presentations remains with healthcare providers. Should a speaker decide to discuss an unapproved use of a product, they must be required by contract to inform the audience of this fact and include a written disclaimer in their presentation.

The PAAB allows distribution of presentation materials to attendees without requiring pre-clearance. If materials are to be further distributed, the distributing pharmaceutical company must ensure that the materials comply with all advertising requirements.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes, it is permissible to pay healthcare professionals to provide expert services provided the compensation is reasonable and reflects fair market value. The agreements must be in writing and a legitimate need for the service must be identified in advance. Selection of the healthcare professional must be solely based on qualification to provide the service. The hiring must not be an inducement to prescribe, and the number of participating healthcare professionals must be limited to the number reasonably necessary to achieve the identified need.

Healthcare professionals may also have codes of conduct or rules surrounding interaction with industry or conflicts of interest and those requirements must also be respected.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Healthcare professionals can be paid for taking part in post-marketing studies provided the study has a legitimate purpose, is in accordance with the *FDA* and *FDR*, and follows an appropriately designed written protocol.

Compensation must reflect the costs incurred in conducting the study, such as professional fees, staff salaries, and laboratory tests. Payment must not be based on continuing administration of the medication after the study protocol has been completed.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Honoraria are permitted provided they are based on industry accepted rates for market research activities and are similar to (and not higher than) the healthcare professional's usual rate of compensation.

The *IMC Code* outlines further requirements outside of payment in order to ensure that the marketing activity is not promotional and to preserve the anonymity of participants.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Non-prescription drugs that have market authorisation, including both over-the-counter drugs and natural health products, may be advertised to the general public subject to the *FDA* and its regulations. Non-prescription drugs and natural health products may be advertised as a preventative for Schedule A diseases, but not as a treatment or cure.

Health Canada has published the *CAG's for non-Rx Drugs*. The guiding principles for such advertisements are:

- no person shall advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety;
- the health and safety of consumers is paramount; and
- advertising should clearly communicate the intended use of the product in a manner that is consistent with the TMA to allow consumers to make appropriate and informed choices.

This document sets out guidelines relating to product characteristics and drug claims and representations. These form the basis on which APAs review DTC advertising of these products.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Prescription medications can be advertised to a very limited degree. As with other advertising, it is not permitted unless the drug has market authorisation. Advertisements to the public must be limited to the name (brand, proper or common), price, and quantity of the drug. This is interpreted very strictly.

Once an individual has been prescribed a medication, they are no longer considered to be the general public, and less stringent advertising restrictions apply.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns discussing particular medical conditions are permitted. Generally, such messages are not considered to be advertising provided they are fair and balanced. These materials can discuss treatment options if all options are presented and their risks and benefits are discussed in an objective manner with no emphasis placed on a particular product. No reference should be made to unauthorised drugs beyond the mention that research is under way and that market authorisation has not been obtained.

Sponsorship alone does not render such materials promotional, however, care must be taken not to link such messages to promotional materials (which can range from materials having a similar look and feel to direct linking through hyperlinks). Such links may cause the disease information to be deemed promotional, subjecting it to the restrictions discussed above.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Press releases are not considered promotional and therefore can refer to prescription medications provided:

- they are directed to shareholders or potential shareholders;
- they are limited to the name of the drug and its authorised or proposed therapeutic use;
- no statement is made regarding the degree of safety or efficacy;
- no comparison is drawn with other treatments;
- for unauthorised drugs or indications, a caution is included that the safety and efficacy are still under investigation and market authorisation has not yet been obtained; and
- there is no attempt to influence the pick-up, placement, or emphasis given in subsequent publication or broadcast.

If any of the above are not met, or if other factors indicate that the purpose is promotional, a press release may be deemed to be advertisement and have to comply with the restrictions discussed above.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Communications that provide details about a pharmaceutical manufacturer such as its philosophy, activities, product range, financial details, or areas of future research are generally considered to be non-promotional, particularly when:

- the purpose of the communication is clearly to provide information about the pharmaceutical company rather than about the drugs being marketed, developed or researched;
- information about the drugs being marketed, developed or researched is limited to the name and therapeutic use of the drug; and
- no emphasis is given to any one or more products, or their benefits.

Where a message does not meet these requirements, it may be promotional and must therefore comply with restrictions discussed above.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Funding can be provided if it is not undertaken for product promotional reasons and is not directed to product promotion purposes. All funding should be documented in a written agreement that acknowledges and accurately reflects the nature of the pharmaceutical company's involvement.

The rules governing meetings would be fact specific and depend on the type of meeting, the content being discussed, and the attendees. Generally, patient groups are not considered to be the general public, and less onerous restrictions would apply although product discussions and would need to be balanced and not misleading in compliance with the FDA.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Companies may provide "service-oriented" items if they are useful as aids to patients' understandings of, or adaptation to, their condition or for encouraging adherence with recommended therapy. These items may bear the corporate name and logo of the company, but must not bear the name of any product. The value of items must not exceed CAD $150.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Drug trials taking place in Canada prior to market authorisation (phase I, II, or III trials) must be registered with Health Canada. Results from these trials are disclosed in the application for market authorisation, and regulations that are in draft at the time of writing would require further publication of certain results. Pharmaceutical companies also have an ongoing requirement to report adverse reactions, which would include those identified in any clinical trial.

The *IMC Code* contains provisions for post-registration clinical studies, however, it does not impose a duty to disclose details.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Unlike in the United States, there is currently no in-force legislation requiring companies to make such information publicly available.

In 2017, some manufacturers began disclosing aggregate data on a voluntary basis.

The Ontario government passed legislation and had posted draft regulations that will put in place a reporting regime. Implementation of the regulations was delayed and there is currently no indication when, or if, they will be. This regime has broad inclusion criteria and, as currently drafted, could include foreign companies.

Currently, Ontario is the only province that has proposed such a regime, although there have been consultations relating to potential reporting legislation in British Columbia.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The *IMC Code* describes standards that member companies are expected to meet. Companies should post a commitment to engage in transparent funding practices on their website as well as a list of all stakeholders to whom they have provided direct funding. Member companies should also be identified on materials to which they contributed financially or in kind. There is no requirement to post the quantum of funding. These requirements apply only to IMC member companies, although other companies may wish to comply voluntarily.

The *CGPA Code* does not require any public disclosure for generic manufacturers.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Disclosure requirements for healthcare professionals, if any exist, might arise from their provincial regulatory body or contractually from a pharmaceutical company. If a manufacturer places contractual requirements to disclose, it could take whatever actions it deems appropriate to ensure compliance.

Under Ontario's proposed regime as currently drafted, if a healthcare professional disagrees with a transfer of value, it will be marked as disputed.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Internet advertising must comply with all standards as previously described. In addition, privacy laws (federal and provincial) would apply if information is collected or used. Canada's anti-spam legislation ("CASL") will apply to messaging and specifically, opt-in consent is required before push messages (including emails) are sent.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Because advertising to the public is restricted, steps must be taken so that websites with information intended for healthcare professionals are not available to the public.

There are no explicit requirements. The *PAAB Code* states that materials geared towards healthcare professionals should provide a "well-controlled entry system". A common mechanism is to require healthcare professionals to enter their licence number to gain entry. Other options include providing healthcare professionals with passwords or providing them with website links that are neither publicly available nor indexed on search engines. Language should also be used on the website to make it clear that content is directed to healthcare professionals.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Depending on the factual context, linking advertising to non-advertising can make the content of both sites advertising. Linking factors include proximity, appearance, sequence, and context. Generally, companies should only link to sites that comply with all advertising regulations, although in certain circumstances it may not be necessary. Such links should also be accompanied by a message indicating that the user is leaving the company's website.

Links from independent websites to corporate pages should link to the corporate global site and should not link to product pages or sections. Again, depending on the factual context, links could make third-party sites advertising, and companies should be cautious when allowing others to link to their website.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Company websites should comply with advertising regulations, limiting prescription drug information to name, price, and quantity. Manufacturers are also permitted to include the Health Canada-approved product monograph on their corporate webpage.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

Generally speaking, pharmaceutical companies are responsible for user-generated content (comments, etc.) on their corporate pages. User content that violates advertising rules, for example, by discussing off-label uses of a drug product, would result in the website being non-compliant. The PAAB has published guidelines for online activities which provides an overview of requirements for online activities and requirements for company oversight.

Of note, should the company become aware of any adverse events, they should ensure that they are addressed according to company policy and applicable regulations.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

ASC introduced a new dispute procedure for complaints between competitors for alleged breaches of the *ASC Code*. The new procedure is designed to further streamline the resolution process for advertising complaints between competitors.

The Ontario transparency legislation that was scheduled to come into force at the start of 2019 was delayed, with no indication as to when or even if it will come into force.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Updates to certain sections of the *IMC Code* are expected in the next year. Health Canada has indicated that it may make changes to monitoring and enforcement, although no official proposals have been made.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There are no enforcement trends that have become apparent in Canada. The number of complaints to the PAAB with respect to prescription drugs remains low.

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# China

East & Concord Partners

Charles Feng

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The most fundamental laws governing advertising of medicinal products is *the Pharmaceutical Administration Law, the Enforcement Regulations on Pharmaceutical Administration Law, Regulations on Medical Advertisement Management, Measures for the Examination of Pharmaceutical Advertisements* and *Standards for the Examination and Release of Pharmaceutical Advertisements*. These laws provide specific rules, measures and standards on governing the advertising of medicinal products.

### 1.2 How is "advertising" defined?

According to Article 2 of *Regulations on Medical Advertisement Management*, 'advertising' indicates any type of advertisement which directly or indirectly gives introduction to medical institutions or services through utilising any kind of media or forms.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

According to Article 7 of *Regulations on Medical Advertisement* Management, Companies with medical qualifications and a licence to practice shall apply to the Health Administrative Department at provincial level for approval on medical advertisements, and provide the following materials: application form for a medical advertisement examination; the original and copy of the duplicate of the licence for practising in a medical institution; and samples of such medical advertisement bearing the companies' seal.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no such requirements for companies to have SOPs or employ personnel with a specific role governing advertising activities.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

According to *Regulations on Medical Advertisement Management*, a medical institution has to pass the application procedure for a medical advertisement examination, and obtain the Medical Advertisement Examination Certificate before advertising. Unless the medical institution makes a self-created outdoor advertisement containing merely its name, logo and contact information in its statutory control area, there is no need to apply for a medical advertisement examination.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Yes, according to *Regulations on Medical Advertisement Management*, if a medical institution violates the provisions of these regulations to issue medical advertising, the health administrative departments or the administrative departments of traditional Chinese medicine, at or above the county level, shall order it to stop advertising and make corrections within a time limit.

The Authorities can order the companies to issue a corrective statement.

The company subjected to administrative punishment can apply for administrative reconsideration to the superior department of the administrative organ within a specified time limit.

### 1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

According to *Regulations on Medical Advertisement Management*, the stipulated penalties for violating relevant laws may include the following:

(1) ordering to make corrections within a time limit;

(2) giving warning, in cases of a serious nature;

(3) revoking its approval for an advertising review and rejecting the advertising review application within a year;

(4) ordering to suspend business for rectification; and

(5) revoking the relevant diagnosis and treatment subjects, or even revoking its licence for practising in a medical institution.

The health administrative departments or the administrative departments of traditional Chinese medicine at or above the county level are responsible for the implementation of these regulations.

Nanjing New Concord Hospital co. Ltd released medical advertisements on television, its own website, its WeChat Official Account and some other media, and the advertisement content is clearly beyond the approved advertisement contents, and all of the advertisement content does not bear the Medical Advertisement Examination Certificate's number, which violated a number of provisions of *Advertising Law*. It was fined 600,000 Yuan by the Local Industrial and Commercial Administration.

In the case where false or misleading information is spread or fabricated to impair a competitors' commercial reputation and commodity reputation, when suspected of unfair competition, the injured party can claim rights through litigation.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The China Association of Pharmaceutical Commerce (CAPC), the self-regulatory body, is obligated to assist the State Food and Drug Administration of PRC (SFDA) on the self-supervision of the pharmaceutical advertising activities, and the CAPC may also protect companies' legitimate interests in the meantime.

Yes, the health administrative departments or the administrative departments of traditional Chinese medicine, at or above the county level, can directly initiate administrative investigations on alleged illegal advertising.

Yes, the SAIC may take up matters based on CAPC's findings.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Civil litigation based on Anti-illegitimate Competition Law can be initiated. And the damaged Party may bring such action.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

According to *Pharmaceutical Administration Law*, when the companies fail to obtain the approval of a local drug regulatory authority of the government of the province, autonomous region, or municipality directly under the Central Government, and a drug advertising approval number, it shall not issue the product information. In general, unauthorised products are unable to obtain the approval number. Therefore, before the product is authorised, the relevant information about the product is not allowed to be released to the public, including healthcare professionals, especially through advertising.

In case of scientific meetings, the information of the unauthorised product may be available to healthcare professionals for the mere purpose of academic discussion.

There is no difference if the meeting is sponsored by the company responsible for the product.

With respect to the unauthorised medicines that have not had a clinical trial approval, the above-mentioned regulations shall also apply.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Companies shall not disclose the specific information of the unauthorised drugs and/or drugs without clinical trial approval to the public. However, companies may release the basic information on unauthorised medicines and/or off-label products for the purpose of academic discussion, or upon the requirements of the CSRC.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

It is not prohibited to issue press releases about unauthorised medicines and/or off-label information.

There are no differences that apply depending on the target audience.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

The company shall not send such information to healthcare professionals.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

According to *Regulations on Medical Advertisement Management*, sending pharmacists the price lists for medicinal products shall be deemed as advertising. And, medicinal products without approval are prohibited for advertisements. Therefore, manufacturers of non-approved medicinal products are prohibited to send the price lists for such products to pharmacists, even for the named-patient/compassionate use purposes.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Information on unauthorised medicines or indications could be sent to institutions for the purpose of budget plans or authorisation.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Companies may involve healthcare professionals in market research exercise. However, such professionals shall not launch specific and detailed information (including the indications) on the unauthorised products.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

According to the *Pharmaceutical Administration Law*, the label or instruction paper must clearly indicate the common name, component, specification, manufacturer, approval number, batch number, date of produce, validity period, indication or main functions, usage, dosage, taboos, untoward effects, and announcements.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

According to Article 10 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, advertisements shall not include: 1) any unscientific assertion or guarantee of effectiveness; 2) a description of the efficacy rate or recovery rate; 3) a comparison to other drugs or therapies in effectiveness or safety; 4) any claims that it violates natural and scientific rules, description or implications of the product being a panacea or "cure-all"; 5) promising words such as "safe", "no side effects", or a description or implications of the product being Chinese patent medicine containing "nature" components, thus having guarantee of safety; 6) words that indicate or imply that the medical product is necessary for daily life or the curing of diseases; 7) words that indicate or imply that the medical device may help the user deal with common life pressures or difficulties, help to improve performance, make the user more energetic, taller or more talented; and 8) other unscientific words or descriptions, such as "newest technology", "top scientific", "most advanced production", etc.

Yes, after obtaining the Approval on Medical Advertisement Examination, an advertisement may refer to studies not mentioned in the SmPC, but the studies shall not contain the names or images of any patient, healthcare professional, medical education or scientific research institution as a testimony of effectiveness.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

According to Article 6 of the *Regulations on Medical Advertisement Management*, the names or images of any healthcare professionals shall not be used as a testimony in the medical advertisement. Thus, endorsements by healthcare professionals are limited in their use in advertisements.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

According to Article 10 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, advertisements shall not include a comparison to any other drugs or therapies in effectiveness or safety. Except for the abovementioned circumstance, the laws, regulations and rules do not have any clear requirements on data from a particular number of clinical trials. However, if no such clinical trial data are obtained before the comparative claims are released, the companies may face the legal risk of false propaganda.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

According to Article 10 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, advertisements shall not include any comparison to other drugs or therapies in effectiveness or safety, or the description of depreciating products of the same kind. Therefore, it is prohibited to use another company's brand name, or even refer to a competitor's product or indication (regardless of whether it is authorised or not).

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Currently, there are no rules governing the distribution of scientific papers.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

According to the *Pharmaceutical Administration Law*, an advertisement must clearly indicate the common name, indications and manufacturer information of the drug. Therefore, generally speaking, "teaser" advertisements cannot be approved.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Yes, the holder of the MA for Product A may rely upon the approved use of Product B with Product A according to Product A's SmPC, and the holder of the MA for Product B may also promote such combination use based on the approved SmPC for Product A.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

According to the *Pharmaceutical Administration Law*, companies are prohibited to provide healthcare professionals (who use the companies' medical products) with any assets or other profits. However, according to *Interim Provisions of Management on Social Donation and Sponsorship to Medical and Healthcare Institutions*, healthcare professionals may accept the samples of medicinal products under the following conditions: 1) such donation must be made under the principles of voluntariness and the *princípio da gratuitidade*; 2) the acceptance of such donation shall not harm the public interest; 3) such donations shall not be made with special conditions which might cause unfair competition; 4) such donations must be made to a legal entity, rather than natural person (such as healthcare professionals) and shall be used and managed by the legal entity; and 5) such donations must be made for the purpose of public benefit.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

According to the *Pharmaceutical Administration Law*, companies producing, selling medical products or providing medical services are prohibited to give gifts or donations of money or any other assets to healthcare professionals. However, according to the *Interim Provisions of Management on Social Donation and Sponsorship to Medical and Healthcare Institutions*, under special conditions, if the companies giving such donations of money require that such donations must be accepted by the natural person (healthcare professionals), approval of the leading group of the institution (where such healthcare professionals work) must be obtained before accepting such donations, and such donations must be managed and used by the financial department of the institution.

Currently, there is no monetary limit for donations.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

According to the *Interim Provisions of Management on Social Donation and Sponsorship to Medical and Healthcare Institutions*, healthcare organisations such as hospitals may accept donations or money, equipment, or funding of medical or technical services under the following conditions: 1) such donation must be made under the principles of voluntariness and the *princípio da gratuitidade*; 2) the acceptance of such donation shall not harm the public interest; 3) such donations shall not be made with special conditions which might cause unfair competition; 4) such donations must be made to a legal entity, rather than natural person (such as healthcare professionals) and shall be used and managed by the legal entity; and 5) such donations must be made for the purpose of public benefit.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

It is clearly stipulated in the *Interim Provisions of Management on Social Donation and Sponsorship to Medical and Healthcare Institutions*, donations which might cause unfair competition are strictly prohibited. Therefore, the provision of any goods or services which might lead to the expansion of the market, or increased market share, through unfair competitions, are strictly prohibited.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

According to Article 12 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, the pharmaceutical advertisement shall not contain any promotional statements including free treatment, gifts, prize-giving sales, providing medicinal products as gifts, etc. Therefore, the offer of a volume-related discount is another way of providing medicinal products as gifts, which is prohibited.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

According to Article 12 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, the pharmaceutical advertisement shall not contain any promotional statements including free treatment, gifts, prize-giving sales, providing medicinal products as gifts, etc. Therefore, providing additional medical or technical services or equipment as the condition for the purchasing of medicinal products is strictly prohibited.

Prescription medicines or non-prescription medicines are strictly prohibited to be used as associated benefits for the purchase of a particular medicine. And providing any non-medicinal products as gifts, which may cause the unreasonable increase in dosage of such particular medicine, is also strictly prohibited. However, in other circumstances, commercial arrangements for providing certain associated benefits (such as apparatus for administration or the provision of training on its use) are acceptable.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

According to Article 12 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, the pharmaceutical advertisements shall promote and guide rational drug use, and shall not directly or indirectly incite patients to excessively or recklessly use medicinal products. Although it is not clearly stipulated that offering a refund scheme when the products do not work is strictly prohibited, the advertisements containing the abovementioned refund scheme will be deemed as encouraging a patient to recklessly use medicinal products, which is actually prohibited. Therefore, regardless of whether it is a prescription-only medicine or an over-the-counter medicine, advertisements containing refund schemes, which may encourage the reckless usage of medicinal products, are prohibited.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Generally speaking, healthcare professionals are prohibited from accepting donations of money from companies, unless approval of the leading group of the institution (where such healthcare professional works) is obtained before accepting such donations, and such donations must be managed and used by the financial department of the institution.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Pharmaceutical companies shall not induce healthcare professionals or healthcare organisations to purchase their medicinal products through giving money or gifts, offering tourist trips or providing reimbursement of expenses for them, and other means of bribery.

Pharmaceutical companies may expressly provide volume-related discounts when selling medicinal products, however, such a discount must be recorded in the financial account. Otherwise, any institutions or persons providing or accepting such discount privately may violate the laws.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

There are no express rules governing the offering of hospitality to healthcare professionals. However, based on the stipulations of the *Pharmaceutical Administration Law* and other relevant regulations of the PRC, healthcare professionals shall not accept the hospitality of pharmaceutical companies privately, and may accept their hospitality or meals during official business.

It makes no difference if the hospitality offered to those healthcare professionals will take place in another country.

Based on the laws and regulations applicable, there are no requirements of obtaining approval of the company affiliate before making such arrangements.

Currently, there is no such threshold applicable to the costs of hospitality or meals provided to healthcare professionals.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

It is possible to pay for a healthcare professional in connection with attending a scientific meeting if such healthcare professional is invited. The travel, accommodation and enrolment fees could be paid.

And if the professional is invited to give a lecture, presentation or discussion on such meeting, it is also possible to pay him for his time.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

According to the *Pharmaceutical Administration Law* and other relevant regulations of the PRC, as in the abovementioned circumstances, a pharmaceutical company shall be held responsible in the following cases: 1) the hospitality arrangements are contingent on the purchase of medicinal products; 2) the hospitality arrangements are provided for the purpose of unfair competition; 3) the hospitality arrangements shall not be provided in private to the healthcare professionals instead of during an official business process; and 4) other cases which may harm the public interests.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

It is possible to pay them for expert services. However, such payment shall not be made with additional conditions, including purchasing their medicinal products, or exceed the average level in a large amount which might be deemed as a bribery.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

It is possible to pay healthcare professionals for conducting post-market surveillance studies. Currently, the *Pharmaceutical Administration Law*, the Regulations on Management of Adverse Drug Reaction Reporting and Surveillance govern such studies.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

It is possible to pay healthcare professionals to participate in market research. However, displaying the name and pictures of such healthcare professionals is prohibited in these promotional materials.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

According to the *Standards for the Examination and Release of Pharmaceutical Advertisements*, non-prescription medicines may be advertised to the general public, but, the medical advertisement must contain the common name, the statement of advice "Please purchase and use in accordance with the drug instructions or under the guidance of a pharmacist", its medical advertisement permission number and its approval number for production.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

It is strictly prohibited to advertise prescription-only medicines to the general public. Besides that, it is also prohibited to release any information about such prescription-only medicines to the general public through providing medical magazines or journals.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Actually, disease awareness campaigns have no rights or qualifications to give suggestions on prescription-only medicines to those with a particular medical condition.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

According to Article 4 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, prescription-only medicines could only be advertised in medical magazines or medical journals jointly designated by the Ministry of Health and the State Food and Drug Administration of China. Therefore, it is impossible to issue press releases concerning prescription-only medicines to non-scientific journals.

According to the *Regulations on Medical Advertisement Management of PRC*, approval of the corresponding health administrative department at provincial level must be obtained before releasing any kind of advertisement. And if the medicines are still unauthorised, it is impossible to obtain such approval. Therefore, it is impossible for the press release to refer to unauthorised medicines or unauthorised indications.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

The corporate brochures/annual reports may also be read by the public, therefore such materials could also be deemed as advertisements, which shall observe the relevant laws and rules on advertising. According to Article 10 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, advertisements shall not include: 1) any unscientific assertion or guarantee of effectiveness; 2) description of the efficacy rate or recovery rate; 3) comparison to other drugs or therapies in effectiveness or safety: 4) any claims that the product violates natural and scientific rules, descriptions or implications of the product being a panacea or "cure-all"; 5) promising words such as "safe", "no side effects", description or implications of the product being a Chinese patent medicine containing a "nature" component, thus having a guarantee of safety; 6) words that indicate or imply that the medical product is necessary for the daily life or curing of diseases; 7) words that indicate or imply that the medical device may help the user deal with common life pressures or difficulties, help to improve performance, make the user more energetic, taller

or more talented; and 8) other unscientific words or description, such as "newest technology", "top scientific", "most advanced production", etc. Except that, description and research initiatives relating to prescription-only medicines are prohibited to be released in corporate brochures/annual reports.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Currently, there are no specific laws or regulations on the meeting-with or the funding of patient organisations. However, with respect to the funding of patient organisations, the following rules shall be observed, according to the Welfare Donations Law of the People's Republic of China: the funding should be made on a voluntary and non-reimbursable basis; any forced apportion or any covert act of apportion will be prohibited; and no one may engage in profitmaking activities of any kind under the guise of funding. The use of funding ought to be based on the will of the fund-provider, and remain in keeping with public welfare purposes. No one is allowed to divert funds earmarked for public welfare to other uses.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Companies may provide items to or for the benefit of patients. But, according to Article 12 of the *Standards for the Examination and Release of Pharmaceutical Advertisements*, the items provided by the companies shall not be medicines or volume-related prizes, which might cause the excessive or reckless use of drugs.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

There is an obligation for companies to disclose the correct details of ongoing and/or clinical trials according to the *Criterions for the Quality Control of Clinical Trial of Drugs*, but currently there is no clear stipulation on such obligation for companies to disclose the complete data of clinical trials.

The above-mentioned obligation is set out in the legislation.

According to the No. 28 Announcement of the SFDA, China is establishing the Platform for the Drug Clinical Trial Registration and Information Disclosure, which may require companies to disclose all clinical trial data in future.

According to the *Measures for the Administration of Drug Registration*, when applying for the registration of drugs, the conclusive materials of the clinical trial shall be provided, which shall disclose the results of the clinical trial and the basic information about the clinical trial.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Currently, there is no such legislative regulation on the requirements of disclosing the information about transfers of value from companies to healthcare professionals.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Currently, there is no such stipulation in the self-regulatory code, which requires the company to disclose any information about transfers of value from them to healthcare professionals.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

The company may not disclose one or more of such transfers.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Internet advertising regarding medicinal products shall observe the same laws and regulations mentioned above.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

According to the No. 87 Announcement of the State Administration of Industry and Commerce issued on July 4, 2016, it is prohibited to use the internet to release any advertisement on prescription-only medicines. With respect to non-prescription medicines, there are no such restrictions on prohibiting the public from accessing the information of non-prescription medicines.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

According to Article 38 of the *Advertising Law of the PRC*, if the

advertisement content violates laws, the advertiser shall be responsible. The advertising agent shall bear joint liability with the advertiser upon knowing or having ought to have known the facts of malfeasance. Therefore, in the case whereby the company's website has the link of an independent website, and if the content of such independent website violates any laws, the company may be held jointly liable with such independent website, upon knowing or having ought to have known the fact of malfeasance. Otherwise, if the company's website content violates any laws, the company shall be held responsible, and the independent website may also be held responsible when knowing or being ought to know such malfeasance.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Only information on non-prescription medicines can be placed online and accessed by the public.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

It is stipulated in the *Standards for the Examination and Release of Pharmaceutical Advertisements*, that a medical advertisement shall not be released on any minor publications, radio and television channels, shows and programmes, etc., and companies are prohibited to use social media to release advertisements for prescription-only medicines.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

In 2017, the State Administration of Industry and Commerce has published three batches of cases on false advertising, which include false pharmaceutical advertising cases. All these cases are of significant meanings for the interpretation and implementation of *the Pharmaceutical Administration Law*.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

We predict that a new Amendment on *the Regulations on Medical Advertisement Management* may be expected in the next year.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Over the last year, it has become apparent that the SAIC and local AIC are more active on taking actions against false advertisement cases, and have put more penalties on companies violating relevant advertisement laws and regulations.

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Mr. Feng is an IP Specialist with substantial experience in intellectual property with reputable International law firms and Chinese law firms, focusing on IP litigation and enforcement as well as trademark and patent portfolio management. Mr. Feng has represented a number of foreign clients from the US, EU, Japan and at various levels of courts as well as enforcement agencies in China.

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天達共和律師事務所
East & Concord Partners

In 2014, the merger between the East Associates Law Firm and Concord & Partners became East & Concord Partners, widely regarded as one of largest and most comprehensive law firms in all of China. The pre-merger firms, East Associates Law Firm and Concord & Partners, were established in 1993 and 1995 respectively, and were both law firms that had extensive influence nationally. Building upon this national reputation, East & Concord Partners has established its headquarters in Beijing, in addition to having offices in Shanghai, Shenzhen, Wuhan and Hangzhou. Globally, East & Concord Partners has created and maintained numerous successful working relationships with many international law firms, which enables our clients to receive the most expedient and best possible service in this globalised world.

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# Denmark

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Chapter 7 of the Danish Medicines Consolidated Act No. 99 of 16 January 2018, (the "Act"), as amended, and Executive Orders Nos 1244 of 12 December 2005 (Samples) and 1153 of 22 October 2014 (Advertising), collectively the "Advertising Order", and executive order No. 801 of 21 June 2013 (Television & Radio), which, together with the Advertising Order, hereinafter are referred to as the "Orders", govern the advertising of medicinal products in Denmark.

In addition to the Act and the Orders, the Danish Health and Medicines Authority (the "DHMA"), has issued guidance note No. 10356 of 29 December 2014 on the advertising of pharmaceuticals (the "DHMA Guide").

The Danish Marketing Practices Consolidated Act No. 426 of 3 May 2017, (the "Marketing Act"), as amended, which basically sets out fair trading standards, governs advertising in general and authorises the Consumer Ombudsman to monitor marketing activities and to sanction non-compliance.

The Act, the Orders, the DHMA Guide and the Marketing Act (collectively, the "Legislative Basis") are enforced by the DHMA and the Consumer Ombudsman.

In addition to said authorities, self-regulated bodies – proceedings before which are possible in addition to administrative and judicial proceedings – monitor the advertising of medicinal, borderline and dietary supplement products, and/or enforce ethical standards. The self-regulated bodies comprise: 1) the Ethical Committee for the Pharmaceutical Industry in Denmark ("*Etisk Nævn for Lægemiddelindustrien*" / "ENLI"); 2) the Marketing Board of the Association of the Veterinary Pharmaceutical Industry in Denmark, Finland, Ireland, Norway and Sweden, ViNordic ("*ViNordic's Marketing Board*" / "ViNordic"); 3) the Pharmacist's Ethical Board ("*ApotekerNævnet*" / "AEN"); 4) the Medical Doctor's Ethical Board ("*Lægeetisk Nævn*" / "LEN"); 5) the Association of Danish Vets ("*Den Danske Dyrlægeforenings Etiske Nævn*" / "DDD"); and 6) the Health Trade Supplier Association's Ethical Board ("*Helsebranchens Leverandørforenings Etiske Nævn*" / "HBL"). Within the scope of their respective statutes, the bodies monitor whether advertising initiatives comply with the Legislative Basis and ethical codes and/or that their respective members comply with applicable ethical standards.

Advertising initiatives addressing doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, midwives, laboratory technicians, clinical dieticians and radiographers, and/or students of such professions (collectively "HCPs"), have been monitored by ENLI since 1 April 2011. Effective as from 1 January 2014, ENLI was transformed into a private limited company, whose entire share capital is held by The Danish Association of the Pharmaceutical Industry ("LIF"). ENLI's jurisdiction, being contractually based, covers the members of LIF, The Danish Generic Medicines Industry Association ("IGL"), The Medicinal Product Parallel Importer Association ("*Parallelimportørforeningen af lægemidler*" / "PFL"), and The Association of Medicinal Product Parallel Importers ("*Foreningen for parallelimportører af medicin*" / "FPM"), as well as corporations and associations, which could have been members of LIF, IGL, PFL or FPM, but have chosen not to be, merely to submit to the ENLI jurisdiction. Although PFL and FPM are separately registered as independent legal entities by the Danish Business Authority ("DBA"), no enterprises having submitted to the ENLI jurisdiction have been identified as FPM members. Consequently, only PFL will be referenced in this guide as the parallel importer association. The Association of Medical Doctors ("LF") and The Association of Danish Pharmacies ("DA"), which were members of ENLI's predecessor, the Legal Board of Self-Regulation concerning Pharmaceuticals ("NSL"), are now, respectively, monitoring medical doctors' co-operation with the industry (conferences, professional consultancies, advisory board memberships, visits by medical representatives and participation in clinical trials), and pharmacists' compliance with a set of DA Ethical Rules, leaving enforcement of advertising initiatives, involving their members to the AEN and LEN, on the basis of the applicable ethical standards alongside the DHMA enforcing the Advertising Order. ENLI's activities are based on a Co-Operation Agreement ("COA") entered into among LIF, IGL and PFL. The current COA version is of 7 December 2018 amending the former versions of 1 May 2018. The COA sets out ENLI's objective, competencies, organisation, management, organs (1st and 2nd instance) and economy. The rules and standards to be enforced by ENLI as per the COA (the "ENLI Rules") comprise: i) an Advertising Codex, Version 2.1 of July 2017, governing advertising *vis-à-vis* HCPs (the "Advertising Codex") incorporating the IFPMA, EFPIA (HCP & Disclosure Codes), the Medicines for Europe ("MfE", formerly the European Generic & Biosimilar Medicine Association, EGA) and the WHO codes on advertising and amended to reflect that FPM has joined ENLI; ii) the Patient Organization Co-operation Codex effective as from 1 January 2017 incorporating the corresponding EFPIA and MfE codices and replacing the former codex version of 23 June 2016 (the "Patient Organisation Co-operation Codex" or the "POCC"); iii) a Donation Codex effective as from 1 January 2017, replacing the former version of 13 May 2016 and addressing donations and grants to hospitals

and certain institutions (the "Donation Codex"); iv) rules on the relations between the industry and the Danish Hospital Sector of 19 February 2015 (the "Hospital Codex"); v) the Lobbying Codex effective as from 1 January 2017 and replacing the former version of 19 February 2015 (the "Lobbying Codex"); and vi) a Joint Statement issued by the LF and LIF providing guidance on the conduct of clinical trials involving medicinal products (including non-interventional trials) in compliance with the advertising rules (the "Joint Statement") taking effect for trials commenced after 1 February 2016. The Advertising Codex, the POCC, the Donation Codex, the Hospital Codex, the Lobbying Codex and the Joint Statement, are hereinafter referred to as the "Codices". In addition, ENLI has issued supplementary guidance notes on: i) Advertising Codex Application Guidance Version 2.5 of 20 April 2018; ii) Guide regarding use of digital media of May 2018 (Version 3); iii) financial sponsorships (June 2016 (Version 1.0)); iv) international congresses (December 2017 (Version 1.1)); v) Pre-Launch of April 2018 (Version 1.0); vi) ENLI Notification Guidance Notes (Undated, No Version No. designated, apparently released on 4 February 2019); and vii) Market Analysis Activities (December 2018 (Version 1.0)). These ENLI guidance notes are hereinafter referred to as the "Guidance Notes". The Codices and the Guidance Notes are available in the Danish language, and some also in the English language, from ENLI's homepage: http://www.enli.dk/.

### 1.2 How is "advertising" defined?

The DHMA Guide defines "advertising" as any information dissemination, canvassing activity or inducement designed (intended to) promote the prescription, supply, sale or consumption of medicinal products. The ECJ's case No. C-316/09, pr. 29 (*MSD vs. Merckle*) recital 29 states that the concept of advertising is very broad. Hence, advertising includes: the promotion of medicinal products to the general public and HCPs; visits by sales representatives; supply of samples; any benefit or bonus, except when their intrinsic value is minimal; sponsorship of promotional meetings or scientific congresses attended by HCPs; and payment of travelling and accommodation expenses for HCPs attending such meetings or conferences. Two types of material are not considered covered by the advertising rules, even if their content as such may be of a promotional nature, namely, a) medicinal information prepared by public institutions aiming to promote rational drug consumption, and b) submission to a HCP of a scientific article on a clinical trial, provided that the article is not commented upon, additional material is not enclosed and the article has been published in advance in a reputable and independent Danish or international journal. This exception even applies to articles summarising comparative medicinal product studies. The advertising definition excludes i) labelling and the accompanying package leaflet comprising the Summary of Product Characteristics ("SmPC"), ii) correspondence, including appendices of a non-promotional nature, needed to answer a specific question about a particular medicinal product, iii) factual, informative safety announcements and reference material, for example, packaging material changes, adverse-reaction warnings as part of general medicinal product precautions (safety) and recall announcements, iv) price lists and trade catalogues, which may comprise product names, forms, strengths, package sizes, prices and pictures of product packages, but not product claims or names of competing products, v) information brochures and homepages relating to human health or diseases, provided that there is no reference, even indirectly, to medicinal products, vi) patient information leaflets provided by a prescribing doctor or the supplying pharmacist, provided that the leaflet only contains objective information of importance to patients and their relatives, and which does not contravene the SmPC, vii) press releases believed to be of interest to the general public from the advertising rules provided that: a) the information offered holds general news value; b) the release is addressing the press; and c) the release is targeting a plurality of journalists or reporters only, for the purpose of having such information assessed and elaborated upon prior to publication by such recipients, and viii) unedited and complete reproductions of package leaflets, the approved SmPC, a publicly available evaluation report and the depiction of a medicinal product packaging, provided that the information made available in such a way that users must actively seek out the information, see ECJ's case No. C-316/09 (*MSD vs. Merckle*). This means that a company may publish, for example, a list of its medicinal products on its website with links to the SmPC and the package leaflet for each drug. For a non-HCP to access the latter, the user must make an active choice, e.g. by activating a link at the marketing authorisation ("MA") holders' homepage directing the user to the relevant document. This condition, which is inconsistent with the SmPC not being considered promotional, implies that the said documents may not be distributed directly to non-HCP users. The Marketing Act, which governs advertising in general, is construed to supplement the scope of the advertising definition to include presentations made in order to promote the supply of goods, advertising which may affect the economic behaviour of the addressee or is likely to injure a competitor (misleading advertising) and advertising comparing competing goods (comparative advertising).

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Under the authority of para. 1–3 of article 68 of the Act, article 17 of the Executive Order No. 1153 on Advertising requires the marketing authorisation holder ("MAH"), or the one advertising, if different from the MAH, e.g. pharmacies, parallel distributors or even third parties without financial interests in the product sales, to store a copy of the corresponding documentation for the advertisement (reference is made to the Damgaard case ECJ C-421/07). The file must be in printed form or digital and, if the latter, in a standard format such as, but not limited to, .pdf, .tiff or .jpeg. In addition, information on the target group, how the advertisement has been distributed, a list of media used and when the advertisement was published must be stored. The documentation must be kept for at least two years and must be made available to the DHMA on request. Advertising material includes not only printed advertisements, but also documentation for non-printed advertisements, such as electronic advertisements made available on the internet. In July 2017, ENLI reached the conclusion that an MAH employee, who used her LinkedIn profile to inform her "followers" that her principal had had a new indication for an existing medicinal product granted, by such behaviour had breached the pharmaceutical advertising rules. The filing requirements can be complied with electronically by maintaining files in generally used and acknowledged formats. The obligations on the filing of the documentation related to donations, see question 4.3 below, are stricter. The DHMA has very broad powers to request copies for enforcement purposes, as it may address anybody who has been involved in the campaign, including advertising agencies. Otherwise, companies are not formally required to have compliance programmes in place.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

SOPs: There are no legal or code requirements for companies to have specific SOPs governing advertising activities. Considering,

however, that companies subject to ENLI's jurisdiction and having breached the norms are required to declare to ENLI that all necessary precautions to avoid repetition have been taken, and that sanctioned non-compliance will be published by ENLI, it is recommended that the Scientific Service see the following, and institute and operate compliance SOPs.

Staff: Article 98 (1) of Directive 2001/83 requires that each marketing authorisation holder establishes a Scientific Service in charge of information about the medicinal products which the holder places on the market. In addition, the Advertising Codex requires that the Scientific Service takes responsibility for the approval and supervision of non-interventional studies. As per the Advertising Codex, the pharmaceutical companies are free to decide how best to establish such service(s), and whether there is one service in charge of both duties or separate services with clearly delineated duties. The Scientific Service must engage a medical doctor or, where appropriate, a pharmacist, who shall be responsible for approving any promotional material before release. This person must certify that he or she has reviewed the final form of the promotional material, and that it is in accordance with the requirements of the applicable laws and other rules, including industry regulations, is consistent with the SmPC and is a fair and truthful presentation of the facts about the medicinal product. The company must also designate staff with a corresponding background to maintain an overview of all non-interventional studies, particularly with respect to any responsibilities assumed by sales representatives. The staff must certify that he or she has reviewed the protocol for each non-interventional study and that it is in accordance with the requirements of the applicable code(s).

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

The Advertising Codex, but not the Legislative Basis, requires electronic notification of, but not pre-approval by, ENLI at www.enli.dk, in case of an ENLI subject:

a) hosting or co-hosting an arrangement (meetings, congresses, symposia, etc.) partially or wholly addressing Danish HCPs;

b) sponsoring *litra* a) arrangements;

c) acquiring access to a sales pitch at a congress in Denmark; and/or

d) publishing, whether in physical media or electronically, advertising materials addressing HCPs.

As per the "Penalty & Fee List" of 1 May 2018 replacing the 1 July 2017 version, each notification triggers a fee of DKK 375 (approximately EUR 50). Notification deadlines for each kind of initiative are set out in § 21 of the Advertising Codex. Generally, the deadlines are 10 days before the event or, with respect to advertising materials, the same day that publication takes place. Invitations must include information that the advertising initiative complies with the above and either that it complies with the Codices applicable or has been pre-approved by ENLI (there is a pre-approval charge of DKK 6,000 + DKK 2,000 per assessment hour required in excess of two (DKK 25,000 for matters of urgency). Amendments to already pre-approved applications trigger a fee of DKK 2,000. All fees are exclusive 25% VAT. If pre-approved, the advertiser cannot be fined, merely reprimanded by ENLI for non-compliance, provided, however, that the information on the basis of which ENLI has pre-approved the initiative has been correct. A reprimand may be given by the ENLI board of appeal if the initiative is found to constitute a breach in spite of pre-approval having been given. The position of the authorities, were they to disagree with ENLI, is not prejudiced by ENLI's position. However, the likelihood of an undertaking being prosecuted under such circumstances is low.

The Minister of the Ministry of Health (the "Minister") is authorised by § 70, para. 2 of the Act to require the DHMA to offer pre-assessment of intended advertising initiatives. Until the Minister may do so, the DHMA is precluded from offering such service. Consequently, the DHMA cannot require an undertaking to submit an intended advertising campaign for pre-approval.

Outside the scope of the Act and the Orders, the Marketing Act authorises undertakings to address the Consumer Ombudsman to obtain an assessment of the legality of intended campaigns addressing the general public.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Both the DHMA and the Consumer Ombudsman have the powers to require that an advertisement be stopped, to require a corrective statement be issued and to take or require appropriate corrective action. The DHMA Guide authorises decisions to be appealed to the Minister, whereas action taken by the Consumer Ombudsman may be brought before the public courts of justice. However, decisions related to radio or television broadcasted advertisements may be appealed to the Board on Radio and Television Commercials, which may involve the DHMA and/or the Consumer Ombudsman in the complaint. The DHMA and the Ombudsman will focus on the breaches of the Legislative Basis. In the absence of such breach, the Codices and the Guidance Notes will not be enforced by the authorities acting *ex officio*. Administrative decisions may eventually be brought before the public courts of justice.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The sanctions for a breach of the advertising provisions of the Act or the Marketing Act range from fines to imprisonment for up to four months (1½ years where non-authorised medicines or fake medicines are involved). A breach of the Orders may be fined.

The DHMA enforces the Act and the Orders, whereas the Consumer Ombudsman enforces, or private interests initiate enforcement of, the Marketing Act, which is construed in accordance with the ICC Code of Advertising and Marketing Communication Practice. Sanctions imposed by the Consumer Ombudsman are subject to judicial review, if required.

The self-regulated bodies enforce their statutes and rules on the basis of their contractual authority. According to the ENLI "Penalty & Fee List" of 1 May 2018 (the "Sanctions"), and ENLI's "Code of Procedure" (the "Procedures") of 1 May 2018, ENLI may impose sanctions ranging from reprimands and fines to public reprimands. In addition, ENLI may require a company in breach to issue corrective statements, recall and/or prohibit the use of illegal advertising material, publish a corrective statement in professional periodicals, and cancel or amend the content of arrangements (conferences, congresses, etc.) planned,

including the sponsoring of such arrangement. Sanctions imposed must be publicly available for a period of no less than two years at the ENLI homepage, provided, however, that only the name of the company in breach is made public, whereas the names of any individuals involved due to data protection legislation, will not be published.

The Sanctions authorise ENLI to impose fines for the breach of rules governing i) advertising material in the range of DKK 30,000 (approximately EUR 4,000 – which has doubled since 2017) for minor, but repetitive, formal errors (1st offence does not trigger a fine), such as a cover letter not being dated, an incorrect INN or API composition, to DKK 150,000 for misleading product claims (which has doubled since 2017), which may compromise public health, and ii) events in the range of DKK 30,000 for, e.g., meal allowance at arrangements lasting less than two hours, to DKK 150,000 for, e.g., meetings abroad with no professional content. Breaches of the Codices on counts other than incorrect advertising material/out of scope arrangements may trigger fines in the range of DKK 30,000 (approximately EUR 4,000) for, e.g., unannounced canvassing visits to hospitals, to DKK 150,000 for contracting patient organisations to promote medicinal products. If several norms have been breached, ENLI may impose an accumulated fine considering all breaches. Individual fine levels for given breaches are predefined in the Sanctions. Under aggravating circumstances, such as repetition of the same breach within any moving two-year period, the fines otherwise applicable may be doubled (maximum DKK 300,000). In a recent case, No. KO-2018-3669 from 17 October 2018, Sanofi was fined DKK 150,000 for repetition of a previously sanctioned Toujeo-campaign comprising several breaches of § 4, para. 2 of the Codex, which stipulates that promotion of a medicinal product must comprise sufficiently complete and objective information and must neither be misleading nor exaggerate the properties of the medicinal product. As per *ultimo* March 2019, 17 cases having closed in 2018 were published including e.g. Eli Lilly in KO-2018-2713 of 7 August 2018, Fine DKK 30,000 (insufficient information), Bayer in KO-2018-2255 of 19 July 2018, Fine DKK 60,000 (unapproved indication/rules for satellite symposia), Novo Nordisk in KO-2018-0114 of 4 March 2018, Fine DKK 40,000 (Comparative Advertising). In cases comprising a breach of the same clause if a company has been sanctioned, it is required to declare to ENLI that the illegal activity has been terminated and that all necessary precautions to avoid repetition have been taken. All decisions made by ENLI, whether in the first instance Scrutiny Board or by the second instance Appeal Board, will be submitted to the DHMA for information.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

A decision made by a self-regulatory body cannot be suspended or prejudiced by appeal to the DHMA. However, a party can bring a case before the DHMA, even though the case has been, or is being handled by a self-regulatory body, whose position may be considered by the DHMA assessing the case. Over recent years, ENLI's predecessor, NSL, sanctioned several companies for having offered to HCPs SMS-services for use by patients, enhancing drug consumption compliance. NSL was of the opinion that the companies, by offering such service, in effect relieved the doctors from work normally vested in HCPs, implying that the services partly constituted financial support to the doctor and partly impacted on the independence of the HCP from the service provider negatively. On request by the NSL, the DHMA scrutinised this practice and reached the conclusion that the SMS compliance service was a service rendered to the patients on a voluntary basis and that doctors were not relieved of any workload, as they are not normally involved in day-to-day compliance monitoring. On this basis, thereof NSL changed its practice, allowing for SMS-compliance services to be offered to patients, although through the prescribing doctor. In principle, such scrutiny by the DHMA can be initiated not only by ENLI, but also by any interest-holding *locus standi*. In a judgment (Case UfR2009-1618S) quoting Case SH2009.V-0132-05, see question 2.3 below: The Danish Maritime and Commercial Court dismissed a suit brought by MerckSerono against Ferring on the grounds that MerckSerono already had identical complaints heard by the NSL and the DHMA, whose decisions were accepted by both parties and implemented by Ferring, which was also fined by the NSL, and that MerckSerono consequently had no legitimate interest in also having the same complaints heard by the court.

ENLI may *ex officio* take up cases regarding companies that are subject to ENLI jurisdiction. As per 13 March 2019, the number of companies subject to ENLI jurisdiction are 79, comprising the members of LIF (37), IGL (11), and PFL (3), companies which are neither members of LIF, IGL nor PFL (27), and associations (1) having submitted to ENLI's jurisdiction voluntarily. ENLI remains in a strong position to enforce its rules against every relevant player on the Danish market, not at least indirectly due to ENLI having resolved to hear cases (see Annual Report 2015, pg. 2) brought by members against non-members, although it obviously cannot enforce decisions in the disfavour of non-members, rather merely hope for the DHMA to notice potential criticism expressed. In the absence of a breach of the Legislative Basis, the Codices and the Guidance Notes will not be enforced by the authorities acting *ex officio*.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The Marketing Act sets out a legal standard requiring any act carried out for a commercial purpose to adhere to fair trading standards. Infringed parties may bring an action before the competent court of justice or may submit a complaint to the Consumer Ombudsman, who may also take action *ex officio*.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

The Act, the DHMA Guide and the "*EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals*" consolidated version 2013 (Statutory General Assembly approved on 6 June 2014), the "EFPIA Code", Section 1.01, prohibit the advertising of medicinal products for which a marketing authorisation has not been obtained as well as off-label advertising. As per §§ 64 and 77 of the Act, advertising is conditional not only upon a marketing authorisation having been obtained, but also – with respect to products that must only be

supplied by pharmacies – on the price applicable having been notified to the DHMA.

In March 2017, however, ENLI issued a first Pre-Launch Guidance Note edition (Version 1.0 amended in April 2018), triggered by a DHMA decision passed on 28 May 2014, which latter decision set up a number of criteria determining whether an activity was to be considered scientific or promotional. On this basis, ENLI has softened its historic position, implying that, *inter alia*, the subjective intent by the "promoter" may play a role in borderline cases. On the basis of the DHMA 2014 decision, ENLI now considers a number of criteria when determining whether an activity is scientific or promotional, e.g. whether the basis for the presentation is scientific, the forum is professional, i.e. that the audience comprises a relatively selected audience, the data is purely scientific, the content and whether the presentation angle has been determined by the lecturers and not by the product proprietor. It is still a "Rule of Thumb" that information cannot be provided on drug candidates for which Phase III data have been published or data been obtained. Generally, this means that Phase I and II data may be presented (assuming that Phase III data are not available) and that an MA cannot be applied for on the basis of Phase II data only, which has been seen for a vaccine being registered under "*exceptional circumstances*" under the authority of article 14 (8) of Regulation 726/2004 and article 22 of Directive 2001/83, on the basis of Phase II data. The distinction implies that product information may be given in the context of a generic suitable presentation environment, e.g. at international congresses. It does not change the situation that the presentation may have been sponsored by the product proprietor. The change comprises a relaxation of the Advertising Codex rules applied in Denmark by ENLI prior to a DHMA satellite symposium decision of 28 May 2014 (the "2014 DHMA decision"), where the access to present product information prior to the MA was more limited than in most other EFPIA countries. The change of practice does not require a change of §§ 64 and 77 of the Act prohibiting advertising prior to the MA having been obtained and a price been notified, as the 2014 DHMA decision merely reflects how §§ 64 and 77 are to be construed. The change brings Denmark in line with most other European countries on this matter.

As per the Pre-Launch Guidance Note, the relaxation does not apply to off-label information in the sense that once a product has been authorised, the presentation of even early stage data on investigated new indications, will consider the promotion of the product as actually authorised. This seems to be a logic consequence of the products actually being available on the market, which creates an increased risk of off-label use, were presentation of expanded indications research to be allowed.

### 2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

The Act and ENLI Rules reflect the requirements of article 87 of Directive 2001/83/EC, as amended (see question 2.1 above), generally prohibiting the advertising of medicinal products, which have not been licensed in Denmark. However, informational material produced by public entities promoting rational drug consumption, see question 1.2 a) above, and scientific articles, which may comprise comparative investigations of drug properties, circulated uncommented to HCPs on an "as are" basis, or, as per question 2.1 above, relating to medicines for which Phase III results have not been published, are normally not considered advertising.

Having said this, the Pre-Launch Guidance Note edition (Version 1.0) referenced in question 2.1 above, authorises dissemination on unauthorised medicines, provided, however, that the criteria for the dissemination not being promotional are met. Hence, "publication" to a wider audience than the very limited number of professionals, who may be the addressees of scientific meetings, will not be allowed, especially not on off-label information, whereas very early scientific data will hardly trigger a sanction, if the sender can substantiate that promotion was not the intention. Information provided by sources independent from the MAH may be caught by the advertising rules, see the *Damgaard* case (C-421/07). As a consequence of this case, ENLI has issued the Digital Media Guidance Note recommending that marketing authorisation holders (the "MAH") must monitor such social media, e.g. Facebook, Twitter, LinkedIn and YouTube, contributed to by the MAH, and remove communications, which may be considered advertising, even if provided by a third party. The scope of the advertising material to be removed is determined by whether the site is accessible to the general public (for which communication the Legislative Basis, but not the Advertising Codex applies) or is available from fora to which only HCPs have access, in which case the Advertising Codex applies. ENLI has, however, also indicated that the MAH cannot be held liable for third-party statements regarding third-party products (e.g. competing products), even if published on a MAH-controlled medium. We do believe, however, that a MAH should remove such statements, as the MAH may easily be challenged under the provisions of the Marketing Act, if not reacted to.

### 2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

The Advertising Codex and the DHMA Guide exempt press releases from the advertising rules provided that: i) the information offered holds general news value; ii) the release is addressing the press; and iii) the release is targeting a plurality of journalists or reporters only for the purpose of having such information assessed and elaborated upon prior to publication by such recipients.

Subject to these conditions being met, the press release will – as a starting point – be falling outside the scope of the advertising rules. If, however, the release includes an identification of named medicinal products, the release may well be considered pre-launch and hence subject to scrutiny as per the 2014 DHMA decision (and hence the ENLI Pre-Launch Guidance Note) criteria. As a press release by definition cannot address only a specific target audience and as a release to journalists can hardly meet the 2014 DHMA criteria, it is not possible for companies to issue press releases about unauthorised medicines and/or off-label information for an authorised product. This does not imply that a company cannot avail itself of the 2014 DHMA decision, but not by means of a press release defined as per the above.

As per the DHMA, press releases may be made available at the relevant company homepages for up to a maximum of three weeks, after which the press release may be considered advertising, rendering the press release exception inapplicable. When drafting articles on the basis of press releases received, the press needs to be cautious, as their articles may easily be caught by the advertising definition; see the *Damgaard* case (C-421/07).

Whether a press release actually qualifies as such or is actually an advertisement, is a balance; see judgment No. V 132/05, passed by the Danish Maritime and Commercial Court on 27 March 2009 (Case SH2009.V-0132-05), quoting a DHMA resolution holding Ferring responsible for having identified medicinal products in what

was classified as a press release, but, as per the DHMA, due to the identification of products in an internet-based release, was actually an advertisement addressing the general public.

On 29 August 2018, the Eastern High Court of Denmark confirmed the judgment passed on 17 March 2018 No. A-46-17 granting Sanofi-Aventis an interlocutory injunction preventing Novo Nordisk from making further use of a "press release" issued by Novo Nordisk on 15 September 2017. The "press release" described the outcome of a clinical study involving the authorised medicinal product Tresiba®. Although Novo Nordisk presumably had intended to describe the outcome of a clinical study named "DEVOTE" collecting data from use of both Tresiba® and Lantus® (Sanofi-Aventis), the header of the release referred to the "Tresiba®-study" rather than to the name of the study, which in combination with the comprehensive scope of the release and unsubstantiated claims made alleging reduced mortality, if severe hypoglycaemia could be avoided, implicitly by use of Tresiba®, qualified the communication as illegal comparative advertising comparing Tresiba® to Sanofi-Aventis' insulin products Lantus® and Toujeo®. The Court reached the conclusion that Novo Nordisk by means of the release had breached the Act, Executive Order No. 1153 as well as the Marketing Act and granted the injunction in combination with awarding costs to Sanofi-Aventis. In our view, it is highly likely that the confirmatory action to be taken will lead to Novo Nordisk being fined.

ENLI's Appeals Board (case AN-2018-2631) followed up on the infringement and imposed a DKK 30,000 fine on Novo Nordisk.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Product information, but not press releases, may be sent to HCPs and others having made a specific enquiry to the company regarding the product properties. Subject to compliance with the Marketing Act's provisions on unsolicited addresses, submission to HCPs of scientific articles containing information on unauthorised products is, in principle, possible, but such must be submitted within the scope of question 2.1 above or uncommented upon, without any additional material being enclosed, and must comprise articles which have been published in an independent and acknowledged Danish or foreign scientific periodical.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

As per § 2, No. 4 of Executive Order No. 1153 of 22 October 2014, price lists and product catalogues that do not contain information about medicinal products other than (trade) names, pharmaceutical forms, strengths, packaging sizes, prices and pictures of medicine packages published on the internet for e-commerce with drugs, do not qualify as advertising, see also question 1.2 iv) above. Hence, making price lists for named-patient/compassionate use purposes pursuant to Article 5 of the Directive available to pharmacists, without this being treated as illegal, is possible. However, the Marketing Act's provisions on unsolicited addresses should be observed together with the 2014 DHMA decision, which may render the message illegal, if the intent of the manufacturer is promotional.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Information on indications can only be provided within the scope of question 2.1 above, whereas price information and product lists can be provided under question 2.5 above.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

As per the 2014 DHMA decision and ENLI's Pre-Launch Guidance Note, market research exercises are possible within the scope of the advertising rules implying that unlicensed products/new indications can be presented, but only to the extent the presentation is required for the HCP to render a specific service contracted. Such HCP must be a medical doctor (human or vet), dentist or pharmacist, but not other HCPs. The HCP must be engaged as a consultant or advisor, individually, or as part of a group, to render a specific service such as evaluating materials. The engagement must be in writing, specifying the services to be rendered and payments to be made, and the contract must be closed prior to the HCP rendering any services. Moreover, the following criteria must, to the extent applicable, be met:

a) a legitimate need for the services must be clearly identified before requesting the HCP to render the same and before closing the agreement;

b) the criteria for selecting HCP consultants should be directly related to the identified need and the persons responsible for the selection of HCP consultants must be competent to assess whether the HCPs meet the criteria;

c) the number of contracted HCPs must not exceed what is reasonably necessary for the MAH to receive the services;

d) the contracting entity shall maintain records of the services received and make proper use thereof;

e) the engagement of a HCP must not imply an incentive to recommend, prescribe, purchase, supply, sell or administer a particular drug;

f) the compensation for the services shall be proportionate and should reflect the real market value of the services provided (symbolic advisory meetings cannot justify payment of any compensations to HCPs); and

g) payment shall only be granted in the form of direct payments of money, and not by off-setting or transfer of assets or other indirect compensation.

From a HCP perspective, the consolidated Danish Health Act No. 1,286 of 2 November 2018, Chapter 61a (Co-operation with the Industry), § 202a, prohibits medicinal doctors (human), dentists and pharmacists from operating or being affiliated with an MAH, unless the affiliation comprises i) education/training (primarily presentations of research results and treatment regimes) or research (primarily clinical research, including non-intervention studies), ii) ownership of MAH-securities, which – when purchased – did not represent a value in excess of DKK 200,000 (≈EUR 27,000) per MAH, or iii) if the MAH is a public hospital. If these conditions are met, the HCP must notify the DHMA of the affiliation, whereas the HCP must apply to the DHMA for approval if the conditions are not met. Applications will be denied if the DHMA finds that the services to be rendered may influence the prescription pattern of the applying HCP,

which, as per DHMA practice, will be the case if the services relate to the preparation of marketing material. As per the Advertising Codex, the MAH is obliged to inform not only the HCPs of their obligations *vis-à-vis* the DHMA, but also the DHMA of an affiliation established between a HCP and the MAH. This double-notification system enables the DHMA to enforce the rules more easily, as the two lists can be compared and omissions identified. The DHMA, which must publish all notifications and applications received on its homepage, has on December 2016 updated its guidance notes on the relations between the industry (medicinal product or device manufacturers/marketers and i) doctors (Guidance Note No. 10360), ii) nurses (Guidance Notes No. 10361), iii) dentists (Guidance Note No. 10362), iv) pharmacists (Guidance Note No. 10363), and iv) and Guidance Notes No. 10364 requiring medicinal product manufacturers, device manufacturers and device marketers to report annually on their relations to doctors, nurses, dentists and/or pharmacists to the extent covered by Guidelines Nos 10360–10363. Said Guidance Notes are unamended as per 1 April 2019.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

Advertisements targeting HCPs must contain the following mandatory information, which must be legible:

1. Trade and generic ("INN") product name(s), i.e. all INN names if a combination.
2. MAH name.
3. Indications for use consistent with the SmPC.
4. Contraindications.
5. Side effects and cautions.
6. Dosage.
7. Product forms (strengths, methods of administration).
8. Package sizes.
9. The purchase price available from www.medicinpriser.dk + pharmacy margin (p.t. 8.2%) + DKK 5.46 (15% reduction compared to 2018) as calculated in accordance with Exec. Order No. 1,693 of 18 December 2018.
10. Supply classification.
11. Reimbursement options.
12. Advertisement version and date.

Information provided must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his own opinion on the therapeutic value of the product.

Information provided for veterinary products must include information on the species covered.

If the advertisement is intended solely as a reminder, the advertisement may comprise the trade name, INN, the MAH and the logo only. On 22 May 2018, Sanofi-Aventis was reprimanded (Case KO-2018-1448 (§ 5, para. 1) for violation of the mandatory information rules, see http://www.enli.dk/media/49736/ko-2018-1448.pdf, by having invited HCPs to a meeting at which Toujeo® and Lantus® would be up for discussion, but without Sanofi-Aventis providing the product information what must accompany advertisements and without the invitation being dated.

Until 1 November 2014, the trade and generic ("INN") product name had to be indicated together with the trade name not only in the header, but throughout the advertisement and by use of similar fonts for both names. These requirements have now been relaxed; the INN name only needs to be indicated once, the font needs to be legible, but not necessarily the same, and logos only incorporating the trade name are allowed if the INN name is provided, where the tradename is first used.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Restrictions: Advertisements, or any other information addressing HCPs, must not contain competitions offering prizes. This prohibition is absolute regardless of whether an individual product is identified or not and regardless of the size and nature of the prize. However, prices for the best abstract or poster may be awarded at arrangements, provided, however, that the price is only used for professional purposes, such as HCP education, congress participation, etc.

Studies: As per the judgment passed in Case C-249/09, *Novo Nordisk vs. Ravimiamet*, an advertisement may include information which is not necessarily included in the SmPC and/or which cannot necessarily be derived therefrom, provided, however, that the claims confirm or clarify, and are compatible with, the SmPC and that the advertisement meets the requirements of Articles 87 (3), and 92 (2) and (3) of Directive 2001/83 as amended. In our view, this judgment is compatible with the Legislative Basis as is.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The DHMA Guide prohibits HCP endorsements in campaigns addressing the general public, but not campaigns addressing HCPs. However, such prohibitions can be found elsewhere, e.g. in LEN's ethical rules, see question 1.1 above, as per which a medical doctor is not entitled to promote medicinal products or products making health claims. Other HCPs may make endorsements, which must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his own opinion on the therapeutic value of the product, implying that endorsements must be qualified and meet the documentation requirements applicable in general.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No, the advertiser may compare products by referring to parameters comprising, e.g., the respective SmPC's, while, however, observing the rules on comparative advertising.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Yes, the advertiser must either ensure that the comparator products can be identified, implying that the advertiser is not only permitted, but almost required, to use a competitor's brand name in comparative advertisements, or provide data on all products available, approved for the indication. The rules governing comparative advertisements are set out in the Marketing Act, the Orders, in the DHMA Guide and in the ENLI Rules. Comparative

advertisements must be based on the SmPCs and must also include supplementary data subsequently generated, provided it is SmPC-compliant, complies with the general advertising rules, compares all relevant and available treatment alternatives, avoids product confusion, be loyal to the comparator products, be objective, and must not take unfair advantage of the reputation of a competitor brand. Effective as from 1 July 2015, the hitherto mandatory table comparing product properties has been abandoned for a trial period, which ended on 30 June 2016. The results achieved during the trial period have been evaluated and in the Annual Report for 2016 ENLI has announced that as no additional disloyalty issues have arisen, the comparison table has now been abandoned for an indefinite period of time. The data provided for the promoted product must include the essential information listed in question 3.1 above, whereas data for comparator products can be limited to therapeutically relevant differences. Outside the scope of the Pre-Launch Guidance Note and hence outside the scope of the comparative advertising rules, it is not possible to refer to a competitor's product, which has not yet been authorised in Denmark, or to an indication of such product if not authorised in Denmark, as such product/indication does not represent a treatment alternative. As per an ENLI judgment (EN-2011-0001), the mere identification of more than one product in an address to HCPs, even addresses that the advertiser does not necessarily consider advertising, e.g. an invitation to an arrangement, will qualify as comparative advertising, requiring the sender to observe the rules applicable for such "comparisons", but it is possible that the 2014 DHMA decision may relax that position.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The Advertising Codex § 4, para. 3, comprises a direct translation of article. 10.03 of the EFPIA HCP Code. This means that promotional information which appears on exhibition stands at Danish congresses or is distributed to participants at international events in Denmark may refer to medicinal products (or uses) which are not registered in Denmark, or which are registered under different conditions, so long as: (i) any such promotional material (excluding promotional aid) is accompanied by a suitable statement indicating the countries in which the product is registered and makes clear that the product or use is not registered locally; and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.). In spite of this code, when it comes to the authority to present scientific papers, etc. to HCPs attending a congress in Denmark, it should be borne in mind that this exception cannot be found in the Act, whose §§ 64 and 77 still require that only authorised and price-notified products can be promoted. Considering, however, the 2014 DHMA decision, sponsors will be able to build up a suitable presentation area meeting the criteria set out in question 2.1, para. 2 above (the presentation basis is scientific, the data is purely scientific, the forum is professional) and thereby be able to present non-authorised products/indications, if the intention is non-promotional. If the products are not registered anywhere, presentation of the scientific papers may take place subject to the 2014 DHMA criteria and the Pre-Launch Guidance Note being complied with. If, however, the sponsor is an affiliate of the Danish LIF member, ENLI may only enforce the ENLI rules *vis-à-vis* the affiliate being a LIF member. This implies that a sponsor may side track/segregate the Danish LIF member affiliate from the congress planning and execution, implying that the foreign sponsor affiliate only has to comply with the 2014-DHMA criteria, but not the Pre-Launch Guidance Note. ENLI has advised that dissemination of scientific data via electronic portals managed by an expert committee is likely to be considered promotion, as the sponsor takes the initiative to the portal and is paying the committee members. *In lieu*, ENLI recommends the use of Advisory Boards.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Neither the Legislative Basis nor the ENLI Rules prohibit the use of teasers, provided, however, that they do not comprise an advertisement of medicinal products. An address to HCPs encouraging the recipient to reserve a given date for an event "to be announced" is not considered advertising and does not need to be notified to ENLI, if the recipient cannot sign up based on the teaser and if the teaser does not include product information.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Part 1: Yes, a MAH holding a MA for combination product treatment of a disease, may promote such combination product use irrespective of the individual MA status for the API's incorporated in the combination product and irrespective of whether any or different rights are held by the MAH or third-party MAHs for either API on a stand-alone basis. Of course, patent and data-exclusivity positions may prevent the combination product MAH from making such promotion, but looked upon from a pure advertising point of view, the MAH may promote any MA's that he holds within the scope of the associated SmPC granted for that specific MA.

Part 2: Promotion of a pharmaceutical must take place within the limits of the SmPC granted for the MA granted for the product itself. Usage not sustained by the SmPC comprises off-label promotion, which is not permissible. The MAH for product B must, in other words, first vary his SmPC for product B, which may be difficult considering the combination product MAH's potential patent and data-exclusivity positions.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Samples of products launched on or after 1 January 2012 may be provided only during the initial two-year period after the launch, and are subject to adherence to the following restrictions set out in the Executive Order No. 1244 of 12 December 2005 (Samples):

1. The recipient must be a HCP, authorised to prescribe the medicinal product in question, who is requesting the sample for a professional purpose that the HCP is licensed to pursue.

2. One sample of each form and strength of a medicinal product may be dispensed per year.
3. The sample must be the smallest quantity marketed.
4. Labelling requirement: "*Free medicinal product sample – not for sale*".
5. A written, dated and signed request must be made by the receiving HCP.
6. Dispensation is made by the MAH representative, not the pharmacy.
7. SmPC must be enclosed.
8. Narcotic/controlled medicinal product samples must not be dispensed.

The MAH must keep accounts of the quantity and type of dispensed medicinal product samples. The accounts, including the requests from the recipients of the samples, must be kept on file for at least two years. Since 2009, it has been possible for a MAH to sub-contract the obligation to keep accounts and to file requests received to wholesalers.

As LF has imposed an obligation for its members, medical doctors, to neither receive nor request supplies of samples, except in very rare circumstances, and considering that a medical doctor will have to request a product sample in a written, dated and signed request format, dispensation of product samples in Denmark will presumably soon be history.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

As per § 22 of Executive Order No. 1153/2014, § 12 of the Advertising Codex, the latter amended to reflect EFPIA's Disclosure Code of 6 June 2014 provisions on gifts, and § 6 of the Donation Codex, no pecuniary advantages or gifts (in cash or benefit in-kind) may be supplied, offered or promised to HCPs, except in connection with i) professional events, sponsorships and hospitality, ii) information and educational material and items of medicinal utility, and iii) donations and grants that support healthcare or research. Even the supply of so-called "leave-behind gimmicks" such as pens, post-it pads, notepads, etc., is no longer allowed, but in connection with arrangements with third parties (no logos or product names) or by the sponsor itself (logos and product names allowed on pens, etc., supplied for the purpose of the HCP taking notes at a specific meeting).

*Re* i) HCPs may receive training and professional information related to medicinal products in the form of payment of direct expenses in connection with professionally relevant courses, conferences, training and scientific events, in which the HCPs participate, or arrange, including by the MAH organising, co-organising or sponsoring events of a mere professional nature and held in "appropriate" venues. Hospitality extended in connection with such events must only be extended to persons who qualify as participants in their own right and must be limited to "reasonable" travelling, meals, accommodation and registration fees (but not to compensate for the time spent). Companies shall not provide or offer any meal (food and beverages) to HCPs, unless, in each case, the value of such meal (food and beverages) does not exceed one of the following monetary thresholds: DKK 400 for lunch; DKK 700 for dinner; or DKK 1,200 covering all meals (food and beverages) at all-day meetings/conferences, etc. The monetary thresholds apply to meals taken in Denmark. When providing meals in other European countries, the monetary thresholds set by the pharmaceutical industry associations in such countries must be complied with. Hospitality must not include sponsoring or organising entertainment (e.g. sporting or leisure) events and the organiser must avoid using venues that are "renowned" for their entertainment facilities or are extravagant and/or luxurious.

*Re* ii) assignment of informational or educational materials to HCPs is permitted provided it is: (i) inexpensive; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients. The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Furthermore, items of medicinal utility aimed directly at the education of HCPs and patient care can be provided if they are (i) inexpensive, and (ii) do not offset the business practices of the recipient.

*Re* iii) donations, grants and benefits in-kind to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare or conduct research (that are not otherwise covered by the EFPIA HCP Code or the POCC) are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Contracts between pharmaceutical companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to companies (or any other type of funding from pharmaceutical companies not covered under these ethical rules) are only allowed if such services (or other funding): a) are provided for the purpose of supporting healthcare or research; and b) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Companies which have not submitted to the ENLI rules may still benefit from the at-present somewhat more liberal DHMA Guide, which allows HCPs, associations of HCPs or members of hospital administrations to receive gifts, provided that the market value does not exceed DKK 300 (approximately EUR 40), including 25% VAT per calendar year, per practitioner, and provided that the benefit can be used professionally (clinical thermometers, calendars and other merchandise directly related to the relevant professional activity) by the HCP. From and including 1 January 2014 LIF members are, as per the ENLI Rules, no longer allowed to provide HCPs with neither "leave behinds" nor gimmicks, irrespective of the value thereof, but in connection with the execution of a conference, where note-taking tools will be permissible.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Yes, donations and grants that support healthcare or research may be provided, see question 4.2. Effective as from 1 January 2017, ENLI's Donation Codex of 13 May 2016, comprising an amendment of the Donation Codex of 7 December 2015, took effect. The amendment limited the scope of the Donation Codex to apply to donations made to institutions, including Danish hospitals, or organisations either comprising HCPs or rendering health or research services. Donations, whether in-kind or pecuniary, must have a professional and/or scientific purpose, including the provision of grants/donations for health services or research, or other professional activities that benefit patient care directly or indirectly. It must be entirely up to the hospital/hospital department

to manage and decide how to make use of the grant or donation. Donations to individual HCPs are not authorised by the Donation Codex. Donations and grants are authorised only if: i) the purpose is to support the rendering of health services or research; ii) the donations are registered by the sponsor; and iii) the donation is not an encouragement to consume, directly or indirectly, medicinal products. Hospital donations must be documented by written and signed documentation specifying at the very least the following:

1) The name of the activity, project, equipment or unit the donation or grant is to support.
2) The name(s) of the hospital/department, etc., responsible for the activity, project, equipment or unit.
3) The name(s) of the person(s) at the hospital responsible for the activity, project, equipment or unit.
4) The name(s) of the person(s) at the hospital responsible for the account (money) or unit (in-kind) to which the donation or grant has been transferred.
5) The name of the competent person, manager, director, etc., at the hospital who has given approval for the hospital/department to receive the donation or grant.
6) The types of activity/project/equipment/unit for which the donation or grant is being given.
7) The purpose of the activity/project/equipment/unit for which the grant or donation is being made.
8) The timeframe (if available).
9) The amount of funding provided.
10) The scope, content and estimated value of benefits in-kind.

ENLI subjects are required to publish a schedule on their website containing the information covered by items 1–2 and 6–10 above. The schedule is to be published when the donation or grant has been made, and shall remain on the website for at least two years thereafter. During the subsequent eight years (10 years in total) the sponsors must be able to provide copies of the schedule on request. Donations made shall be reported annually via a template published by ENLI. The sponsor must monitor that the funding granted is actually spent as agreed in the written documentation that must be signed by the parties. Certain calendar year *de minimis* thresholds of DKK 5,000 for specific activities or purposes and DKK 20,000 if identical in-kind contributions (needles, refrigerated transportation boxes, etc.) are provided, relieve such sponsors from complying with a number of obligations, i.e. to have the donation approved by two hospital staff, compliance with the documentation requirements 1–10 above, to publish the sponsoring on their homepages and to report annually to ENLI on the scope thereof. There are no upper limits for sponsoring taking place in accordance with the Donation Codex.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

If provided within the scope of permitted HCP activity funding, i.e. authorised as per an exception to the general rule that HCPs must not receive financial benefits, donations will be legal even if they may lead to a change in the prescription pattern or in the allotment of market shares among the MAHs. As sponsorships are limited to costs associated with strictly professional and scientific activities, and to activities whose content cannot be influenced by the sponsoring company (unless the sponsoring company is (co-) organising itself, in which case corresponding limitations apply), potential changes in the prescription pattern as a result of the arrangements will *per se* be the result of acceptable training and presentation of material, which is balanced.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted? If monetary limits apply, please specify.**

Although discounts will always comprise an economic advantage to the receiver, which as per Exec. Order No. 1153/2014 § 22, para. 1 is prohibited, § 36 of the same Order exempts product discounts, which may be offered for all drugs to retail dealers, including pharmacies, provided that the discount is based on cost savings for the supplier as a direct result of volume savings or similar "cost-based discounts". No monetary limits apply, provided, however, that the rebate cannot exceed the savings realised. Permitted cost-based discounts include all drugs. The rules on access to provide cost-based discounts only apply to the relationship between supplier (whether a manufacturer, importer or wholesaler) and the retailer. Any discounts agreed between companies within the pre-retailer distribution chain, for example, between manufacturers/importers and wholesalers, are not covered by the rules on cost-based discounts. Pharmaceutical manufacturers and importers that make their own deliveries to retailers are, on the other hand, subject to these cost-based discount regulations.

Cost-based discounts should be calculated in relation to the supplier's direct and indirect costs, such as administrative expenses, payroll, inventory, transportation, etc., associated with the delivery of the drugs to pharmacies or other retail outlets. Cost-based discounts may comprise arrangements implying a reduced supply frequency/higher volumes per delivery, which imply supplier savings as a result of lower costs per delivery and reduced administrative/handling costs. If a retailer, for example, goes from five weekly deliveries to one weekly delivery, a discount may be offered, if the supplier's standard terms are five weekly deliveries.

The retailer may also show flexibility in delivery times. Thus, a pharmacy holding its own stock of medicines may accept a certain irregularity in relation to the supplier delivery times, enabling the supplier to arrange an appropriate and cost-effective delivery and hence to offer rebates reflecting such logistical improvements.

Cost-based discounts cannot be justified by a unilateral introduction of new general cost-saving technology at the wholesale level, but need to reflect savings achieved through retailing outlets rationalising their purchasing behaviour.

Voluntary associations of pharmacies – pharmacy chains – may negotiate agreements on cost-based discounts on behalf of all chain members. The discount obtained must not, even partially, be accumulated in the association, but must benefit the members directly.

The discount must comprise a price reduction of the products included in the actual delivery triggering the discount. The cost-based discount must be clearly stated on the invoice, or a credit note issued immediately after delivery, to indicate how it is calculated, and it must be separate from discounts granted on products not covered by the restrictions. Bonuses must not be provided to the end-users of medicinal products, whether individuals or patient groups, neither directly nor indirectly. However, the hospital

owners, the Regions, may be granted a bonus in connection with the sale of products to a hospital. If the purchaser reduces the number of deliveries by building up a bigger stock, it is possible to credit the purchaser for subsequent AIP reductions for a limited amount of medicines per every 14-day period.

**4.6 Is it possible to offer, to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

No, in relation to retailers, § 36 of Executive Order No. 1153/2014 requires rebates based on cost savings to be granted in the form of price reductions and not in the form of other services or benefits. Rebates, as well as the calculation basis for same, must be indicated in the invoice. Replacing the grant of a rebate by invoicing for services rendered separately will constitute a *quid pro quo* arrangement implying a breach of § 36 and hence comprise if not a criminal kick-back, see question 4.9 below, then at least an unauthorised rebate comprising a breach of Executive Order No. 1153/2014. If an offer was made in response to a tender, such offer would be inconsistent with the tender terms and be unacceptable to Amgros, representing the hospital owners.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

A refund scheme can be and has been offered for certain products. The supply status is irrelevant in this situation. The refund principle reflects that some patients may not enjoy the envisaged benefits of taking the prescribed medicinal products in spite of the medicinal product being contractual. In June 2004, the DHMA announced that Novartis had launched a "pay back" scheme for Diovan®, noting that the DHMA, while not approving the campaign (which the DHMA cannot), did not consider the campaign as being a breach of the Act *per se*. However, the DHMA noted that such campaigns represent a challenge to the reimbursement system. Subsequently, the DHMA has accepted that Bayer is entitled to offer financial compensation to doctors who have to dispose of a Mirena® (levonorgestrel-releasing intrauterine device ("IUD")) as a result of the IUD having become unsterile. On the basis hereof, Bayer applied to the DHMA for permission to replace an unsterile IUD with a sterile one free of charge rather than providing financial compensation. The DHMA resolved that such procedure would comprise advertising and be inconsistent with Exec. Order No. 1153/2014 in spite of no competing products, but parallel-imported Mirena® IUDs being available in the market place. The decision was appealed, but upheld by the Ministry of Health in a decision made on 12 November 2013. It appears that Bayer has now decided to cease the replacement policy applied, which was greatly appreciated by the GPs, without considering other replacement models.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

The Advertising Codex § 13 authorises the sponsoring of (continued) medical education to an individual HCP carrying out a training programme, whose scope is entirely professional, whose content the sponsor is fully aware of, but does not influence in any way and which in no way whatsoever is promotional. The latter condition is also decisive for the sponsoring not being caught by § 22, para. 1 of the Act. If these conditions are met, e.g. Ph.D. projects may be sponsored directly, whereas undefined "training tuitions" cannot be paid for and training in administrative systems or organisational development cannot be sponsored.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Whereas no specific anti-bribery rules apply to pharmaceutical companies, HCPs and HCOs, the Danish Penal Code Consolidated Act. No. 1156 of 20 September 2018 does contain two anti-bribery provisions, namely §§122 and 299. These provisions apply to the bribery of civil servants and persons abusing fiduciary positions, respectively.

§122 stipulates that anyone who provides, gives or offers benefits or advantages to civil servants or other persons holding public offices, for the purpose of the recipient exercising public duties in a given manner, may be imprisoned for up to six years.

§299, para. 2, contains a supplement as per which an administrator of third-party financial interests, may be imprisoned for up to four years, if the administrator – through his administration – obtains benefits or advantages for himself or others. The punishment described also applies to anybody, who may have offered the administrator the benefit, etc.

Breaches of the Penal Code will be investigated by the Police, normally following receipt of a report from an aggrieved party. If the alleged breach of the Penal Code also implies that the Legislative Basis has been breached, the Prosecution Service may file suits demanding punishment not only for the breach of the Penal Code, but also for the breach of the Legislative Basis. Obviously, the Prosecution Service will not consider either the ENLI Rules or the Guidance Notes, but breaches thereof may be enforced simultaneously by ENLI, which will consider breaches thereof independently of the Penal Code breaches. There is no reason to believe that the Prosecution Service will postpone their dealing with the Penal Code alleged breaches pending a DHMA or ENLI conclusion of their investigations, as Penal Code breaches can be pursued without prejudicing the ability of the DHMA and/or the ENLI to consider the promotional advertising rules on a standalone basis and to impose sanctions on the offender irrespective of the results achieved by the Prosecution Service.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Expenses in connection with promotional, educational and scientific campaigns arranged for HCPs may be sponsored, whereas non-professional activities such as entertainment, sightseeing trips, etc., may not.

Hence, support may be granted for the renting of premises, study materials, fees and travel expenses for lecturers, participant payment and hospitality costs. In cases where sponsored events are held away from the participants' normal places of work, the business may bear the costs of travelling and accommodation for the participants.

Expenses are, however, only to be reimbursed upon presentation of an invoice and travelling should take place by reasonable means of transportation. Endeavours shall thus always be made for the mode of transport and accommodation standards to be reasonable, implying that First Class travelling will always be prohibited. Hospitality expenses must be kept at a reasonable level and be subordinate – with respect to finance, as well as time – to the professional purpose of the event, which – for food (other than sandwiches, fruit and low-cost beverages) to be served, see question 4.2 on value thresholds – must exceed two hours' duration. For accommodation at a hotel to be sponsored, the event must last at least six hours and be continued the following day.

The approved cost limits include beverages, VAT and tips. Full transparency is required with respect to identification of the meeting organiser, the purpose of the arrangement, any financial support given and by whom.

No company should organise or sponsor an event taking place outside Denmark unless justified by logistics, i.e. that the majority of the invitees are from abroad and/or the event, for reasons outside the control of the company, takes place abroad. For events abroad, the thresholds applicable in that foreign country are applicable, i.e. that each "EFPIA country" determines the locally applicable thresholds applicable to arrangements to be held in that country. There is no requirement in the ENLI rules that a Danish LIF member must obtain approval by its local affiliate of events taking place in that jurisdiction. However, co-ordination is recommendable as the local affiliate may be considered liable in its own right for breach of the local rules, if the local affiliate participates in the event.

As per § 202b of the Health Act, see question 2.7 above, HCPs must report sponsor contributions received for travelling abroad to the DHMA.

As for any other arrangement, ENLI must be notified in advance of any event addressing Danish HCPs and sponsored by a member, any sponsorships and a member's lease of a stand at a congress. The notification must contain information on the purpose and aim of the arrangement and who the organisers are. The invitation to the participants must confirm that ENLI has been or will be notified prior to the arrangement being held and the company must state that the arrangement complies with the Codices or has been pre-approved by ENLI. In addition, notification must take place in the country in which the company affiliate offers the hospitality, if required as per national rules.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Yes, direct expenses to a meeting participation, whether educational, scientific or promotional, as well as payment or reimbursement of expenses defrayed for meals, travelling, accommodation, and other professionally relevant activities in which a HCP participates or which a HCP is hosting, can be sponsored. However, such expenses must be "reasonable" and must be offered solely to the extent relevant for the permitted advertising activity and solely in close connection with the same timing-wise. HCP remunerations cannot be made on the basis of loss of income or time consumption as such. The criterion is the arm's length value of the service provided.

Companies must make sure that any financial support is used for the purpose intended, and – if the support is given to private individuals – that all expenses are accounted for.

Social activities, expenses in connection with the entertainment of spouses and other arrangements falling outside the approved objective of the arrangement cannot be sponsored.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

The DHMA does not apply *absolute maxima* for the sponsoring of HCP costs. However, the language used also calls for costs not to be excessive, so were the DHMA to consider a matter where a MAH had sponsored an event, it is likely that the DHMA would take inspiration from the Advertising Codex thresholds.

ENLI subjects, on the other hand, are subject to the Advertising Codex and must, hence, comply with notification obligations and act prudently in ensuring that the arrangement and the scope of the hospitality to be offered lies within what is acceptable under the Codices. Whether the meeting is directly sponsored or the sponsorship is a contribution to a third-party arrangement, the company must make sure that the scope of the intended sponsorship is proportional to the arrangement as arranged or described. If the sponsored arrangement breaches the Codices by means of excessive hospitality or the like, the company will, in principle, be exposed to liability even if the sponsorship is indirect. The Codices do not make a distinction based on a degree of guilt assessment. Hence, companies also sponsoring third-party arrangements have to make sure that the Codices are complied with.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes, HCPs may teach at meetings or render services to the sponsor against a reasonable cash remuneration, whereas the offering of values in-kind and of reimbursement is prohibited by § 24 para. 2 of Executive Order No. 1153/2014 (reference is made to question 4.2 above). Subject to DHMA approval, doctors, dentists and pharmacists may become members of Advisory Boards, directors or

assume other positions, which in theory may impact the prescription pattern. Companies engaging HCPs must report such engagements to the DHMA. Furthermore, any relevant and reasonable travel and accommodation expenses in connection with such arrangements may be paid for, whereas social activities cannot be sponsored. Focus groups must be used with care, as the advertising rules must be complied with when the participants are involved in the discussions required. The mere approval by the DHMA for a HCP to render their services in connection with serving, as a focus group member does not relieve the sponsoring company from the obligation to comply with the advertising rules.

### 5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

A HCP may participate in a post-marketing surveillance study and may receive payment for services rendered in connection herewith, subject to observing the restrictions set out in question 2.7 above. Whereas post-marketing non-interventional studies are subject to the ENLI Rules, clinical pre-marketing trials are subject to DHMA and ethical committee jurisdiction and hence not monitored by the ENLI. However, the rules on venues, entertainment, use of consultants and transparency apply to all studies, whether pre- or post-marketing. The Joint Statement signed on 18 December 2014, clarifies the values that form the basis for HCPs and companies co-operating on trials and non-interventional studies. The Joint Statement aims to ensure that the involved interests are independent. Although non-intervention trials do not require approval in Denmark by the DHMA or ethical committees, the Joint Statement suggests that trial plans should be submitted to the DHMA, which has undertaken to provide guidance on whether a trial is an intervention trial or a non-intervention trial, and – in response to a specific query – render guidance on the rules on promotion and its interpretation associated with non-intervention trials.

### 5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Yes, HCPs may be compensated for taking part in market research within the scope of § 24 of Exec. Order No. 1153/2014 and sec. 5.6.2 of the DHMA Guide, which reads as follows: "*The prohibition against providing financial benefits for healthcare personnel does not cover payment for services from individual healthcare personnel or a pharmacy if the fees are commensurate with the service provided. [ ] Fees may only be paid in money*." Accordingly, HCPs may only receive payment for a service to a pharmaceutical company if the service forms part of a normal, mutually obligating agreement between the person and the company and if the service and consideration are commensurate. This might, for example, be payment for doctors' professional assistance in undertaking clinical trials or drawing up information material on medicinal products. It could also be remuneration to a HCP, who sits on an advisory board, who is to be a speaker at a professional event or who provides services in connection with a market research.

ENLI introduced a guide on market research in December 2018 which, in terms of payment of HCPs, is in line with the above cited Exec. Order and the DHMA Guide.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Advertising of non-prescription medicines to the general public is in general permitted, provided that the medicinal product can be used without diagnosing and/or no medical supervision is required.

Advertisements addressing the general public must inform the addressee that this is an advertisement promoting medicinal products and the advertisement must contain certain data, e.g., name, the package sizes, prices, indication, side effect, dosage, and an encouragement for the patient to check-out the patient information leaflet.

When advertising on film and radio, the requirements regarding package sizes and pricing do not apply.

The Orders provide that TV commercials must contain certain information to be announced on the screen or by a speaker, including the name and effects of the medicinal product and significant side effects. In addition, the addressee must be encouraged to read the package leaflet, to read more about the application of the pharmaceutical product on the tele-text pages of the TV channel concerned, and to look up the website of the MAH.

The 3 April 2019 guidelines No. 9296 of 1 April 2019 regarding Over-The-Counter medicines was issued (The OTC Guidelines). The OTC Guidelines instructs the MAH to include the below information in advertising directed at the general public when such advertising is placed in a pharmacy; e.g. a poster in a pharmacy containing information regarding a pharmaceutical is regarded advertising. Also, when a MAH pays the pharmacy for placing their product on a given spot in a pharmacy, the mere placing of the product in this spot results in such activity being regarded as advertising.

In order to ensure the credibility of the commercial and to avoid bringing information which could confuse ordinary consumers, the Orders contain 14 types of information that are prohibited, including: (i) statements claiming that common wellbeing may be reduced if the medicinal product is not used; (ii) recommendations by HCPs encouraging consumption of medicinal products; and (iii) discussions on fatal diseases or symptoms thereof. In advertisements, addressing the general public on the use of HCPs, or HCP look-a-likes, is not permitted.

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No, the Act prohibits advertising of prescription-only medicines to the general public.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Disease awareness campaigns are not considered as advertising if no medicinal product is identified, which was confirmed by ENLI on 31 January 2012 in case AN-2011-2486. To avoid disease awareness campaigns falling within the scope of the advertisement definition, the campaign must focus on the disease, whereas neither the cure nor products should be mentioned.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

In theory yes; in practice no. Although the Pharmaceutical Advertising rules do not apply to press releases containing brief, objective information on a medicinal product, which has general news value, with the press as the target group and circulated or made available to a multiplicity of journalists or the media with a view to journalistic review and processing prior to publication, a release comprising POM information will be considered advertising, as the mere mentioning of POMs will be considered promotional, even if the content is objective content and non-misleading. Also, if payment is made for a press release to be printed in the media, it is regarded as advertising irrespective of the content.

A pharmaceutical company can make a press release available to the media in the press room of its website for about three weeks. After that, it will no longer be regarded as having general news value and may, after a specific assessment, be regarded as advertising. However, the industry needs to act responsibly considering the risks represented by the *Damgaard* case and the DHMA resolution quoted above under question 2.3, if the recipients of press releases are not familiar with pharmaceutical advertising. It might be worthwhile for the industry to consider adding a disclaimer to their releases summarising the key findings of the *Damgaard* case. With respect to unauthorised medicines, press releases can be released subject to the company complying with the Pre-launch Guidance Note, whose guidance presumably will also be accepted by the DHMA, when it comes to press releases made by non LIF-members.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures / Annual Reports?**

Annual reports and other general information addressing stock market/investors, or other addressees falling outside the scope of HCPs, such communications often include texts referencing medicinal products and indications being researched and developed, but not yet authorised. For inclusion of such information in material distributed to non-HCPs to be acceptable, it has to be assumed that the capacity in which the recipient is receiving the information will determine whether the exception applies or not. Otherwise investors, who also happen to qualify as HCPs, would not be entitled to receive information distributed under the exceptions otherwise applicable; see below. As per the 2014 DHMA decision, see question 2.1, it is now clear that the subjective intent of the sponsor may impact on whether published materials are considered promotional or not. As long as corporate brochures and annual reports are only distributed to investors, analysts and stock exchanges for the purpose of promoting investments in the company and not the individual products (to be) marketed, such documents will not be caught by the advertising definition in the Orders or the Advertising Codex.

If, however, the brochures and Annual Reports are used by the sponsor to address HCPs in their capacity as such, product information included in brochures and Annual Reports may cause the same to be caught by the advertising definition.

In this respect, ENLI has included an amended version of the EFPIA Code guidelines on website content (Annex B to the EFPIA Code) in the Advertising Codex. As per Section 2, websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programmes, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicine advertising law. This exemption allows the publication of Annual Reports, which often contain descriptions of development programmes and expected product claims, and will have an impact on the scope of the information allowed in announcements to investors that is exempt from the Advertising Codex.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

"*Danske Patienter*" (Danish Patients), http://danskepatienter.dk/about-danish-patients, is an umbrella organisation whose members comprise 20 patient organisations, representing 82 patient associations, having some 880,000 members. MAHs may sponsor patient organisations subject to compliance with the POCC, which requires transparency through all sponsorships being made in a written contract identifying the parties, the project sponsored, the type of project (contributions to general activities/specific arrangements, informational campaigns, etc.), the objective, the roles of the parties involved, the period of time for the sponsorship, the support budget, the costs that can be covered and non-financial support, if any. All contracts must be publicly accessible via the homepages of the sponsors for the duration of the co-operation and for at least six months after. On request, a copy of the contracts must be supplied to anybody who is interested. LIF companies co-operating with patient organisations must annually submit a report to LIF identifying the organisations sponsored. Further, the POCC defines standards applicable for companies sponsoring meetings, compliance with the Legislative Basis at all times, non-exclusivity and legal capacity. Representatives from Patient Organisations may be used as speakers and be remunerated subject to contracts to this effect being closed, fairly much as per the principles applicable to HCP Consultancy Agreements.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Per definition patients are considered the general public in relation to the Legislative Basis and the Advertising Code. The Advertising Code prohibits wining, dining and accommodation from being offered to the general public in connection with advertising campaigns. However, support may be granted for all activities, projects and purposes within the sphere of the organisation's work, as long as it is non-promotional. Professional activities should always be the main intention of the collaboration. Services must be proportionate to the compensatory measures. Events organised or sponsored by, or on behalf of pharmaceutical companies, must be held at a suitable location that contributes to the main purpose of the event, and which is not renowned for their entertainment facilities or is too extravagant. Catering and hospitality associated with events must be limited to expenses for transportation, meals, accommodation and fees for participation. All kinds of catering and hospitality must be reasonable in level and strictly limited to the purpose of the event. In connection with events, the company's hospitality must not include sponsoring or organising entertainment of any kind (e.g. sporting, culture, music or leisure events). Catering and hospitality may only be offered to persons who qualify as participants in their

own right. In exceptional cases, catering and hospitality of an accompanying person who meets health/supporting/caring needs (e.g. as a helper) can be provided.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

All authorised clinical trials must be registered in publicly acknowledged and accessible registers such as www.clinicaltrials.gov or www.clinicaltrialsregister.eu, which is acknowledged and supported in the Joint Statement, see question 1.1 above. These requirements originate from the principle of the Helsinki Declaration that both negative, as well as positive findings, should be made public. The principle has now been re-confirmed in article 25, para. 6 of the 536/2014 Clinical Trial Regulation. During the trial, § 89 of the Act requires a sponsor to notify the DHMA i) immediately, if unexpected serious adverse reactions occur, ii) within 15 days, if a sponsor needs to abort the trial, in which case the DHMA must be informed of the reasons, and iii) annually, of all serious adverse events incurred and subject to safety. Within 90 days from close-out the sponsor must inform the DHMA hereof and without undue delay, and in any case within one year after close-out, submit the trial result to the DHMA.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

§ 21 of Exec. Order No. 1153/2014 requires that patient organisations publish on their website all economic benefits, including financial sponsorships, whether in cash or in-kind, and their value/scope, that the organisation has received from MAHs (in that case the marketing authorisation triggers the reporting requirement). The information must be made available on the websites within one month after the patient association has received an economic advantage, and must be available on the website for at least two years.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

By means of LIF, IGL and PFL, and hence all of their members having adopted "*EFPIA's Code On Disclosure Of Transfers Of Value From Pharmaceutical Companies To HCPs And Healthcare Organisations*" ("EFPIA's Disclosure Code"), full transparency is required irrespective of whether the recipient is a HCP, Healthcare or Patient Organisation. As a company, to become an LIF member, it is necessary to be active in research, development, manufacturing or commercialisation of medicinal products, the transparency rules also apply to companies that have not yet been granted a marketing authorisation, and to foreign companies, provided, however, that they are actually members of LIF, IGL or PFL. The transparency principles are reiterated in § 3 of the POCC, § 10 of the Donation Codex and the introduction chapter ("General") to the financial sponsorship Guidance Note. The POCC requires that contracts meet certain minimum standards, that they are publicly accessible at all times via the internet and for at least six months after the termination of the co-operation, that copies of contracts no older than 10 years are handed out on request, and that the company annually and before 31 December submits a list to ENLI of all co-operation projects. ENLI publishes these lists. Moreover, as per § 10 of the Donation Codex, each donation made to hospitals must be published on the donors homepage, when the donation has been granted and must remain accessible for as long as relevant, and at least two years. A copy of the list shall be handed out on request, when no longer accessible on the homepage, although donations older than 10 years do not need to be included. This list shall also be submitted to ENLI annually upon elapse of the calendar year reported. Finally, the financial sponsorship Guidance Note encourages companies to request that sponsored events are fully accounted for by the company receiving accounts for the sponsored events.

As per the EFPIA Disclosure Code, disclosures shall be made within six months after the end of the relevant reporting period, and the information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed, unless, in each case, (i) a shorter period is required under applicable national data privacy laws or other laws or regulations, or (ii) the recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked. The companies and interests affected will be those subject to ENLI jurisdiction. It may be noted that the reporting standards required by the Codices and the Guidance note differ from those of the ENLI Disclosure Code.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

If the company informs the HCP of the company's obligation as per the Advertising Codex to notify the DHMA of the affiliation established between the HCP and the company, see question 2.7 item f. above, we trust that the HCP will realise that non-disclosure is not an option.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Advertising over the internet of medicinal products is covered by § 9 of Executive Order No. 1153/2014 and the Digital Media Codex, which stipulate that such advertising must comply with the requirements of the Legislative Basis, as must advertisements published in physical media. Unless internet-based campaigns are password-protected, they are considered to be addressing the general public.

ENLI issued the Guide regarding use of digital media in advertising activities (The Digital Media Guide as amended in May 2018). The Digital Media Guide stems from Annex B to the EFPIA's Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, and the guidelines are supplements to this code.

The DHMA and ENLI are monitoring internet advertising (see question 8.4 below); often in reaction to complaints submitted by competitors to advertising companies. If the advertiser is based outside Denmark and if the local affiliate of the advertiser has not been involved, ENLI has no jurisdiction to interfere. The DHMA, however, may be able to enforce the Legislative Basis when advertising is aimed at the Danish public or HCPs, reference is made to C-173/11, *Football Dataco Ltd., et al. vs. Sportradar GmbH*.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

The DHMA Guide and the Digital Media Codex require sites addressing HCPs to be restricted in an efficient way by a unique username, in conjunction with a personal password being required for accessing the homepage. If such precautions are not taken, the information provided will be considered as having been made available to the general public, i.e. illegal advertising.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Advertising on the internet is subject to the same requirements as the requirements applicable to advertising in other media, and there are no special rules for references made to external links. Activities with social media that are controlled or influenced by a company must be monitored and controlled by the company, as it may otherwise incur liability for third-party statements which are not in compliance with the advertising rules. Hence, the company must, on a regular basis, monitor the site and remove all illegal or non-compliant statements. It is unlikely that a company will be made liable for the content of independent websites whose content is not controlled or inspired by the company in question. However, it is nevertheless recommended that the company incorporates a disclaimer which positively informs the reader that the homepage contains links to external sites over which the company has no control and for which the company consequently is not willing to assume responsibility. Placing such disclaimers on the homepage, however, will not relieve the company from the requirement to verify that external links referred to maintain a certain standard. If sites referred to are persistently sub-standard and perhaps even subject to legal or other actions initiated by authorities, competitors or other third parties in the market, the upholding of references to such may expose the company to negative public exposure.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Advertising of non-prescription medicines to the general public is generally permitted, provided that the medicinal product can be used without diagnosing or medical supervision being required. Advertisements addressing the general public must inform the addressee that this is an advertisement promoting medicinal products and the advertisement must contain essential information; see question 6.1 above. In May 2009, the DHMA required two MAHs to withdraw advertisements released on their homepages. In the case of Pfizer, the DHMA found that information on the homepage regarding Carduran® Retard should be considered as advertising. Such advertisement could be accessed by members of the public and was therefore prohibited. In the case of GlaxoSmithKline, the DHMA resolved that, while the information on the homepage qualified as an advertisement for non-prescription medicines, the information mandatory as per question 6.1 was not indicated, implying that the DHMA required the advertisement to be withdrawn.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The use of social media in connection with advertising activities is now governed by the Digital Media Guide of May 2018, Version 3.0. The Digital Media Guide requires advertising using digital (previously referred to as "social") media to comply with the requirements of the Legislative Basis and includes numerous practical advice on the administration.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

In 2018, ENLI and most of the Danish Public Hospitals entered into a collaboration agreement regarding the pharmaceutical industry's collaboration with HCPs employed in such hospitals. The main idea is that all conference invitations must be directed to the head of department at the hospital who will then assign the proper employee. Also, ENLI must be informed of such invitation.

ENLI published in late 2018 the guide on market access including a Q&A and a template for neutral market access, which will not be considered advertising.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

The ENLI focuses on transparency and on increasing the general knowledge about ENLI and its activities only among LIF, IGL and PFL members, as well as among other stakeholders in the pharmaceutical environment, such as patient organisations.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

Employees and their behaviour on digital media has been under scrutiny. In ruling KO-2017-2276 of 7 July 2017, an employee of MSD Denmark, posted a product-related message via her private LinkedIn account. This post was not addressing HCPs, but the general public. Although ENLI confirmed that MSD, having demonstrated that the company diligently had trained their

employees on how to use digital media in compliance with the rules for pharmaceutical advertising, was in compliance, while noting that the ENLI Rules did not authorise ENLI to fine the perpetrator (namely the employee having breached the rules) ENLI eventually concluded that MSD Denmark had actually violated the Advertising Codex § 4, No. 2. MSD received a DKK 15,000 fine. No appeal was filed although it appears that MSD "took one for the team".

In 2018, an Amgen employee was, in line with the *Damgaard* principles, found personally liable for a post on LinkedIn. In the landmark case, the first ever from the Danish Medicines Agency, referred in the media on 21 March 2018, but did not publish by the agency, that Amgen Denmark was acquitted in a case where an Amgen employee had shared a US press release regarding one of Amgen's medicinal products. The agency found, unsurprisingly, that sharing a press release on digital media comprises a communication to the general public (see question 2.3 above on press releases), for which sharing the employee was found liable, although no sanction – due to concrete circumstances – was imposed on the employee.

More generally, in 2018, ENLI continued controlling and sanctioning members to ensure compliance with Danish law and the international, mainly European, ethical codes applicable to the pharmaceutical industry. In 2018, ENLI received 5,053 notifications, a reduction from 5,228 in 2017. The ENLI panel of investigators reviewed 39.5% of the 2018 notifications against 48.3% of the 2017 notifications. 98.5% of the activities were approved, whereas sanctions were imposed in 1.4% of the cases evaluated, triggering fines in only 0.7% of the cases, reflecting a high compliance ratio. Although the number of fines remain low, the income derived from the fines increased slightly, primarily due to fine increases. Fines are primarily imposed when notifications are not made in time or where submissions are incomplete. All decisions which impose a sanction on a company are published (in Danish) on ENLI's website, www.enli.dk. In general, ENLI is satisfied that companies subject to its jurisdiction strive to comply.

In 2018, updated versions of i) the Advertising Codex (practise clarifications as hitherto communicated via News Letters, changes regarding the description of indication, changes of graphs and figures, as well as clarifications regarding the hand-out of meeting equipment), the Patient Organisation Co-operation Codex (all members are now obligated to inform ENLI directly of contracts with, and donations to patient organisations, which information ENLI will publish at www.enli.dk), the Donation Codex, the Lobbying Codex (Scope and application), and ii) Guidance Notes for the Advertising Codex, international congresses (group liability for breach of the rules, satellite symposia, exhibition stands and communication of third-party scientific information), pre-launch, and on use of digital media, took effect. Moreover, ENLI kept the fine levels, primarily due to one major case.

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Jan was born in 1963 in Copenhagen, Denmark. In 1991, after graduating from the University of Copenhagen (Master of Laws) in 1987, and after having completed a training programme in the Copenhagen City Law Firm Møller, Tvermoes & Hoffmeyer, Jan was admitted to the Bar and was granted High Court advocacy rights.

In late 1991, Jan joined the Lundbeck group and was appointed General Counsel thereof in 1994. As General Counsel, Jan participated in the conclusion of numerous pharmaceutical industry transactions with cross-border implications, including the acquisition and divesting of product rights, joint ventures and strategic licensing and alliance arrangements, primarily in Europe, Japan and the United States of America. In addition, Jan was responsible for the casualty insurance programmes of the group, a responsibility that led to Jan being appointed General Counsel and Executive Vice President in 1999 of a globally operating reinsurance group, whose operations were ceased in 2004 as a result of the 9/11 2001 attacks on the USA.

In 2004, Jan established Jusmedico Law Firm ("Jusmedico"), which now represents leading Danish biotech companies, R&D-based pharmaceutical operations and academia on legal and regulatory issues, manufacturing, clinical testing, international alliances, product liability and insurance matters. To enable the rendering of legal services on the basis of non-legal competencies, a Jusmedico Advisory Board was formed in 2007. The Advisory Board now comprises eight professionals whose individual professional competencies and experiences are complementary to each other; see www.jusmedico.com under "Advisory Board".

Jan primarily advises on the legal implications of R&D activities (medicinal products and devices) and cross-border co-operations, and is the secretary and treasurer of BioLawEurope. He is also the contact person for Ira Nordlicht, who is in charge of Jusmedico's New York representative office.

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Martin Binzer Lind was born in Rønne, Denmark in 1977. In 2013, after graduating from the University of Copenhagen (Master of Laws) in 2004, being admitted to the Bar in following completion of a training programme in Advodan Glostrup, Martin was matriculated at the University of Alicante, Spain, where he obtained a LL.M. degree in intellectual property rights in 2013.

From 2013–2015 Martin worked as a business developer for the hospitals in the Capital Region of Denmark. From 2015–2017 Martin was mainly serving as legal counsel to a listed Danish Biotech Company in all matters related to research and development, intellectual property strategies and the general data protection regulation ("GDPR") in the EU and Denmark. In 2018, Martin joined Jusmedico as a Partner.

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Jusmedico is a specialist law firm providing legal services to the biotech, pharmaceutical, medical device and dentistry industries, life science investors and suppliers and service providers thereto.

The working areas of Jusmedico include, without limitation, biotech start-ups, capital raising and re-funding activities, research and development, pre-clinical tests ("GLP") and clinical trial ("GCP"), manufacturing and supply ("GMP"), labelling and packaging, licensing, marketing alliances (co-promotion & co-marketing), agent and distribution agreements ("GDP"), advertising and promotion, pricing and reimbursement, and parallel imports of pharmaceuticals and insurance issues related to all of said working areas, including product liability claims.

Internationally, Jusmedico is a founding member of the BioLawEurope F.m.b.A. alliance, comprising a network of independent European law firms and individual attorneys providing legal services in the same fields as Jusmedio. Further, Jusmedico operates a representative office in New York, USA.

Jusmedico is regulated by the Danish Bar and Law Society and audited by Ernst & Young LLP, Copenhagen.

In 2017, 2018 and in 2019, Jusmedico was awarded the Corporate INTL Global Award Price as *Biotech Law Firm of the Year in Denmark*.

Chapter 10

# England & Wales


Silvia Valverde

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products in the UK is controlled by a combination of legislation and codes of practice.

The main regulations are found in Part 14 of the Human Medicines Regulations 2012/1916 (the Regulations). The Medicines and Healthcare products Regulatory Agency (MHRA) supervises the advertising of medicinal products on behalf of the licensing authority. The Regulations are supplemented by guidelines published by the MHRA; mainly the Blue Guide – Advertising and Promotion of Medicines in the UK, September 2014 and general guidance published on the MHRA website.

While the UK Government has not discarded the possibility of achieving an agreement with the EU in relation to the arrangements following the UK's departure from the EU, on 1 April 2019 it issued a new draft statutory instrument, the Human Medicines (Amendment etc.) (EU exit) Regulations 2019, that will amend the Regulations to ensure that they are fit for purpose in the event of a no deal EU exit scenario.

In a no deal scenario, the MHRA needs to operate as a regulator outside the EU system and to take on roles formerly carried out by the EMA as well as to reflect reciprocal arrangements currently existing between the UK and EEA Member States. The provisions of the draft statutory instrument do not affect the requirements applicable to the advertising of medicinal products which are already controlled and enforced at national level only. Its amendments to Part 14 of the Regulations are limited to the introduction of the term "UK" before all the references to marketing authorisations.

In addition to enforcement by the MHRA, most pharmaceutical companies operating in the UK agree to self-regulation in accordance with industry Codes of Practice, controlling the advertising of medicines and related activities. The Association of the British Pharmaceutical Industry Code of Practice (the ABPI Code), administered by the Prescription Medicines Code of Practice Authority (PMCPA), regulates the advertising of prescription-only medicines (POM); the latest version came into operation on 1 January 2019 The Proprietary Association of Great Britain (PAGB) Consumer Code regulates the advertising of over-the-counter medicines to the general public and the PAGB Professional Code regulates the advertising of over-the-counter medicines to persons qualified to prescribe or supply. The Codes of Practice repeat the law but, in several respects, go beyond the legal requirements. Companies who have not agreed to abide by the relevant Codes of Practice and the associated self-regulatory mechanisms are supervised directly by the MHRA.

Further to the controls which specifically relate to medicines, other general legislation, such as the Trade Descriptions Act 1968, may in principle be applicable. Commercial practices (including advertising) relating to consumer goods are subject to a series of laws on trading of consumer goods, including the Consumer Protection from Unfair Trading Regulations 2008 (business-to-consumer practices) and the Business Protection from Misleading Marketing Regulations 2008 (business-to-business practices). The MHRA works with the Advertising Standards Authority (ASA), the UK's independent regulator for general advertising across all media, and the Committee of Advertising Practice (CAP), the body responsible for writing and maintaining the UK Advertising Codes and providing authoritative advice on the rules, to maintain high and consistent standards.

### 1.2 How is "advertising" defined?

"Advertisement" is defined in section 7 of the Regulations, as "anything designed to promote the prescription, supply, sale or use" of a medicinal product. This is stated to include: door-to-door canvassing; visits by medical sales representatives to persons qualified to prescribe or supply medicinal products; the supply of samples; the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind (except where the intrinsic value is minimal); the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, including payment of expenses.

The Regulations state that the definition of "advertisement" does not include: packaging; correspondence answering specific questions about a medicinal product (which may be accompanied by material of a non-promotional nature); and reference material and announcements of a factual and informative nature (including: (i) material relating to changes to a medicinal product's package or package leaflet; (ii) adverse reaction warnings; (iii) trade catalogues; and (iv) price lists), provided that no product claim is made.

The ABPI Code does not define "advertising", but uses the term "promotion". Promotion under the ABPI Code is stated to cover "any activity undertaken by a pharmaceutical company or with its

authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines" (Clause 1.2). The 2019 version of the ABPI Code has added "risk minimisation material" to the list of activities and materials excluded from the definition of promotion.

The Court of Justice of the European Union (CJEU) has clarified the definition of advertising and the persons subject to EU advertising rules. In particular, Article 86(1) of Directive 2001/83/EC (the Directive) provides a definition of advertising that focuses on the purpose of the message and the objective pursued, i.e. if the intention is to promote the prescription, supply, sale or consumption of medicinal products, it is advertising (C-316/09 MSD). It is not necessary for the message to be disseminated by a person linked to the manufacturer and/or seller of the medicinal product or to be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising (C-421/07 *Damgaard*). However, the prohibitions, for example, in relation to the provision of financial inducements, do not apply to national authorities pursuing public health policy, including any policy on the public expenditure on pharmaceuticals (C-62/09 ABPI).

The dissemination of information that is a faithful reproduction of the approved package leaflet or summary of product characteristics (SmPC) of a medicinal product is unlikely to be considered advertising, although the selection, manipulation or rewriting of any such information can likely be explained only by a promotional purpose (C-249/09 *Novo Nordisk*).

**1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?**

Companies who supply POMs and have agreed to abide by the ABPI Code should make sure that all relevant personnel involved in the promotion are appropriately trained on Code requirements. Although companies may have different internal procedures and guidelines for reviewing material, promotional material must not be issued unless its final form has been certified by a person on behalf of the company. This person must be different from the person responsible for developing the material.

Materials that will be printed can be certified in electronic form by a company signatory in the usual way; however, such material must not be used until the company signatory has checked and signed the item in its final printed form (in those circumstances, the material will have two certificates and both must be preserved). The signatory should be a registered medical practitioner or a pharmacist registered in the UK. UK-registered dentists may also certify promotional material if the product is for dental use only.

All promotional materials must be certified, regardless of format (e.g. printed or electronic, audio and audio-visual). The following materials must be certified in a similar manner: (i) educational material for the public or patients issued by companies that relates to disease or medicines, but is not intended as promotion for those medicines; (ii) material relating to working with patient organisations; (iii) material prepared in relation to joint working between the NHS and the pharmaceutical industry (only the final documents need to be certified); (iv) material relating to patient support programmes involving the provision to healthcare professionals of items to be passed on to patients; and (v) non-promotional material for patients or healthcare professionals relating to the provision of medical and educational goods and services issued by companies. Material that is still in use must be recertified at intervals of no more than two years. Certificates and accompanying material must be retained for at least three years after the final use of the material. There is no need to certify or examine meetings which involve travel outside the UK if the only involvement is sponsoring a speaker to present at a meeting and the pharmaceutical company has not participated in the arrangements for the meeting in any way.

Companies must have a scientific service to compile and collate all information (whether received from medical representatives or from any other source) about the medicines they market.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

There are no legal requirements for companies to have specific SOPs. The ABPI Code includes a section on "Guidelines on company procedures relating to the code of practice". These guidelines provide that in order to assist with compliance, companies should have a comprehensive set of SOPs covering all aspects of the ABPI Code. SOPs should establish high standards, and companies are expected to ensure that relevant staff are trained and validated on their content. The guidelines require pharmaceutical companies to have written documents setting out the representatives' instructions on the application of the ABPI Code to their work, and a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure. The ABPI Code provides that each company should have a senior employee who is responsible for ensuring that this document meets the requirements of the Code. There is an assumption that this responsible person is the managing director or chief executive or equivalent unless other formal arrangements have been made within the company. In addition, and in line with the requirements of Directive 2001/83/EC, the Regulations require marketing authorisation holders to establish a scientific service to compile and collate all information relating to the product. This legal requirement is mirrored by the ABPI Code.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

The Regulations do not require the advance approval of advertising. However, the MHRA has the power under section 304 of the Regulations to issue a notice requiring any person concerned with the publication of advertisements relating to medicinal products to supply copies of advertisements prior to publication and not to use those advertisements until they have been approved. It is a criminal offence to fail to comply with such a notice. Circumstances in which pre-use vetting may be required include: (i) where a newly licensed product subject to intensive monitoring is placed on the market; (ii) where a product is a reclassified product; for example, from prescription-only to pharmacy; or (iii) where previous advertising for a product has breached the Regulations. Pre-use vetting may also be requested as a result of a major new indication for use or where there are safety concerns. In addition, the MHRA has committed to vet initial advertising for all new active substances.

The duration of the vetting is commonly two to three months, and does not normally extend for longer than six months. This period can be reduced or extended depending on the quality of the initial advertising material submitted and other relevant factors.

It is also open to companies to seek guidance from the MHRA on proposed advertisements or to request a meeting to discuss issues that arise during the vetting procedure.

The ABPI Code does not require any prior approval for the advertising of POMs, but again, guidance can be sought prior to publication. MHRA vetting does not guarantee compliance with the ABPI Code.

In the case of over-the-counter medicines, the PAGB Consumer Code requires prior approval. However, this requirement does not apply to advertisements aimed at persons qualified to prescribe or supply medicines, or their employers (caught by the PAGB Professional Code). The PAGB reviews all of their members' advertising to the public against their code of practice.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The MHRA has the power, under sections 304, 305 and 306 of the Regulations, to issue notices prohibiting the publication of specified advertisements. Where the MHRA notifies a company that it is minded to consider an advertisement to be in breach of the Regulations, the company has the right to make written representations to the Review Panel. The findings of the Review Panel have to be taken into consideration by the MHRA before a final decision on how the company promotes its product can be made. If the MHRA issues a final notice determining that an advertisement is in breach, the company has no further right of appeal and will commit a criminal offence if it proceeds to publish the advertisement. The company may also be required to publish a corrective statement.

While there is no appeal mechanism, it is open to the company to challenge the legality of a notice issued under section 306 of the Regulations by means of judicial review. In practice, this is unlikely to be successful unless the MHRA's procedure was demonstrably unfair.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Enforcement of the advertising provisions of the Regulations is the responsibility of the Enforcement Group of the MHRA. In most cases, a person (including a company) who contravenes the legislation faces an unlimited fine. In addition (or alternatively), where individuals are involved in the publication or use of unlawful advertising, a period of up to two years' imprisonment may be imposed.

Prosecutions for advertising offences are extremely rare. A prosecution for illegal advertising relating to activities addressed to healthcare professionals has not occurred for many years. More recently, prosecutions have concerned products that are claimed to have medicinal properties, but that are not authorised as medicines, or advertising to the general public of POMs via the internet or otherwise. The MHRA prefers to resolve complaints quickly and informally, with companies agreeing to take voluntary action to amend their advertising and, in some cases, to issue a corrective statement. Details of cases resolved informally are posted on the MHRA's website.

The ABPI Code is administered by the PMCPA, and complaints made under the Code are considered by the PCMPA's Code of Practice Panel. The parties to a complaint have no right to appear or be represented before the Panel, but may appeal decisions made by it to the Code of Practice Appeal Board, which includes representatives of industry and the medical professions, chaired by an independent lawyer. Administrative charges are payable when a company is found in breach of the ABPI Code (£3,500 per matter for ABPI member companies, or £12,000 if the matter is unsuccessfully appealed). The Panel and/or Appeal Board also have the power in serious cases to require an audit of a company's promotional procedures or to refer the matter to the ABPI Board of Management, who may suspend or expel the company from the ABPI or direct that the company should no longer be included in the list of companies who have agreed to be subject to the ABPI Code of Practice (with the result that the company becomes subject to direct supervision by the MHRA).

The PAGB does not impose any financial sanctions, but a company may be expelled from the PAGB if it has failed to comply with the PAGB Code.

Generally, it is unusual for competitors to take direct action through the courts, although they can make complaints to the MHRA, PMCPA and PAGB. Legal proceedings by companies are only possible in the case of an action based on defamation, slander of goods or an infringement of trademark rights (see question 1.9).

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The relationship between the self-regulatory process, administered by the PMCPA, and the supervisory and enforcement function of the competent authority, the MHRA, is set out in a Memorandum of Understanding between the two bodies and the ABPI. The two systems are regarded as "complementary and synergistic", but the self-regulatory system does not oust the jurisdiction of the MHRA. Both bodies can hear complaints from whatever source, save that the MHRA would normally refer inter-company complaints to the PMCPA, and may refer other complaints to the PMCPA with the consent of the complainant. The MHRA will routinely decline to investigate cases where it is aware that these are under investigation by a self-regulatory body, but reserves the right to take action if serious public health concerns are raised or if self-regulation fails (e.g., if the sanctions imposed by a self-regulatory body do not seem to deter a company from committing further material breaches of the rules). It is possible that material pre-vetted and approved by the MHRA might subsequently be ruled by the PMCPA as in breach of the ABPI Code. The MHRA regularly reviews information on the PMCPA website about the consideration of current cases and may investigate the case further when the PMCPA proceedings are completed.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

UK legislation does not create a separate offence of unfair competition. Setting aside breach of the advertising rules, there is the option of taking action based on trademark law, passing off, trade libel or malicious falsehood. A trademark infringement action may be brought by the owner of the trademark that has been infringed. A passing-off action may be brought by a party whose goods are being misrepresented to the public as being the goods of another party, provided the party in question can show sufficient goodwill or reputation in the product and that such actions have caused damage to the claimant. A trade libel or (if malice can be demonstrated in relation to a statement) malicious falsehood action may be brought by a trading corporation or company whose reputation is damaged.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Section 279 of the Regulations prohibits the publication of advertisements for any medicinal product unless the product in question has a marketing authorisation, a traditional herbal registration, a homoeopathic medicinal product certificate of registration or an "Article 126a authorisation" (products authorised for justified public health reasons).

The supply of unlicensed medicinal products for individual patients in the UK is governed by Part 10 of the Regulations. Section 167 permits the supply of unlicensed products in certain circumstances, and if certain conditions are met. The conditions include a requirement "that no advertisement relating to the medicinal product is published by any person".

The proactive provision of information by a pharmaceutical company about an unauthorised medicine or about the unauthorised use of a medicine is very likely to be seen as a promotion in breach of the Regulations and the ABPI Code. There are certain exemptions, in certain circumstances, such as replies made in response to individual enquiries from members of health professions or other relevant decision makers, discussions at international meetings organised by learned societies, advance notification of new products to the NHS or the legitimate exchange of medical and scientific information during the development of a medicine. However, each one of these activities must be considered on a case-by-case basis as the context in which the exchange takes place and the audience will be important factors in determining whether the activity is acceptable.

Clause 3 of the ABPI Code sets out rules for the promotion of medicines that are not licensed in the UK at international meetings taking place in the UK. Where these meetings are truly international and of high scientific standing with a significant proportion of attendees from outside the UK, it is possible to display information on medicines that are not authorised in the UK, but are authorised in at least one other major industrialised country. This is also the approach taken by the MHRA Blue Guide.

The position is the same regarding the provision of off-label information.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Information of genuine scientific interest that is not promotional may be published in relation to both unauthorised medicines and off-label use. If the publication has been sponsored by a pharmaceutical company, such sponsorship must be clearly indicated.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

It is possible to issue press releases about unauthorised medicines and off-label use to both professional and general audiences, provided that the releases concern a matter of legitimate scientific interest (for example, the results of a pivotal clinical trial) and are not promotional in tone. For example, the trade name should be used in moderation and sweeping claims should not be made. The tone and content must be accurate, factual and balanced.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Upon request, such information can be provided to healthcare professionals. Any activity that appears to be designed to solicit such requests is likely to be considered promotional.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Following the decision in Case C-143/06 *Ludwigs*, the definition of "advertising" (which appears in section 7 of the Regulations) was amended to exclude price lists. Accordingly, licensed manufacturers and suppliers of unlicensed medicines are not prohibited from circulating price lists to healthcare professionals to whom the price of unlicensed products may be relevant (e.g. potential customers and budget managers). The ABPI Code clarifies that price lists

relating to unlicensed medicines are not considered to be promotional provided that they include no product claims, and make it clear that the products are unlicensed. Such price lists can be sent to healthcare professionals and other relevant decision makers at reasonable intervals or in response to enquiries, and without first having received an unsolicited order. They must not be used proactively in a manner that could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

The MHRA advises in its guidance on the supply of unlicensed medicinal products that any price list supplied should only consist of a basic line listing providing the following information: reference number; medicinal product name (British-approved name or equivalent); dosage form; strength; pack size; and price.

### 2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

The ABPI Code expressly recognises that NHS organisations and others involved in the purchase of medicines need to estimate their likely budgets in advance, and therefore require information about the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure. Accordingly, information may be provided in relation to products which contain a new active substance (or an existing active substance prepared in a new way) which has a significant new indication or a novel and innovative means of administration. The information must be directed only towards those responsible for budgets and not to prescribers and it must be made clear whether the product has a UK marketing authorisation. The likely budget implications must be indicated and must be such that they will make a significant difference to NHS expenditure. The information must be limited to factual material, and should not be in the style of promotional material. The MHRA Blue Guide also recognises that such information may be provided "exceptionally".

### 2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The ABPI Code states that, "market research is the collection and analysis of information, and must be unbiased and non-promotional". The use made of such information and statistics may be promotional, but these two phases must be kept distinct. The British Healthcare Business Intelligence Association (BHBIA) has also produced guidelines on market research entitled "The Legal and Ethical Framework for Healthcare Market Research" (current version issued in July 2018).

On the basis of the ABPI Code and the BHBIA guidelines, it is in principle acceptable to enter into agreements with healthcare professionals for *bona fide* consulting services, including market research activities. Market research exercises concerning launch materials for unauthorised products are permissible, provided they do not constitute a platform for disguised promotion to healthcare professionals. In this regard, it is crucial to define the objective of the market research, which will decide the number of healthcare professionals that it is reasonable to involve. Any materials used should be strictly non-promotional. It is preferable to use generic names where possible.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

Section 294 and Schedule 30 of the Regulations state that, with the exception of abbreviated advertisements, all advertisements to healthcare professionals must contain essential information compatible with the SmPC and must contain the following:

- a marketing authorisation number;
- the name and address of the marketing authorisation holder (or that part of the holder's business that is responsible for the product's sale or supply);
- the classification of the medicinal product (i.e. POM, P or GSL);
- the name of the medicinal product;
- a list of the active ingredients, using their common names and placed immediately adjacent to the most prominent display of the name of the product;
- one or more of the product's indications for use, consistent with the terms of its marketing authorisation;
- a succinct statement of the entries in the product's SmPC relating to (i) adverse reactions, precautions and relevant contraindications, (ii) dosage and method of use, and (iii) method of administration (where not obvious); and
- the cost (excluding VAT) of the product.

Abbreviated advertisements are defined in section 295 as advertisements no larger than 420 square centimetres that appear in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply medicinal products. They must contain essential information compatible with the SmPC and the majority of the information required for a full advertisement, but can refer to a website with information on adverse reactions, precautions, contraindications and methods of use rather than including this information in the advertisement itself.

The general requirements in relation to advertisements do not apply to advertisements intended to be solely a reminder of the product, and that consist solely of the name of the product or its international non-proprietary name or trademark. In the case of a registered homoeopathic medicinal product, this could also be the scientific name of the stock or stocks or its invented name.

These rules apply to international journals where these are produced in English in the UK (even if only a small proportion of their circulation is to a UK audience) and/or intended for a UK audience.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

In Case C-249/09 *Novo Nordisk*, the CJEU concluded that Article 87(2) of the Directive prohibits the inclusion in advertising of claims that conflict with the SmPC. However, not all of the information contained in an advertisement needs to be identical to that in the SmPC, provided the claims are consistent with the information in the SmPC. Advertisements may, therefore, include additional claims, provided that these confirm or clarify (and are compatible with) the information set out in the SmPC. Any such additional information must also meet the various other requirements of the Directive, such as being presented objectively, faithfully and in such a way as to allow independent verification,

and not being exaggerated, misleading or inaccurate. This reflects current practice in the UK. Clause 3.2 of the ABPI Code states that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SmPC.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Section 289 of the Regulations prohibits the publication of advertisements relating to a medicinal product that refer to recommendations by scientists, healthcare professionals, or persons who, because of their celebrity, could encourage the use of the medicinal products.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Controlled "head to head" clinical trial data are not required to support comparative claims, although the availability of such data will inevitably assist in demonstrating that statements are balanced and can be substantiated. Presentations of weak comparative data from individual studies may be judged as misleading, and all relevant data must be presented to ensure a fair and balanced comparison. Differences that do not reach statistical significance must not be presented in such a way as to mislead. Before statistical information is included in promotional material, it must have been subjected to statistical appraisal.

The MHRA has stated that, where secondary end-points are being used to promote a product, primary end-point data and the limitations of the data must be included in order to ensure readers are not misled. Comparisons must relate to clinically relevant endpoints.

Where data from clinical trials are used as substantiation for any claims made, the trial must be registered and the results disclosed in accordance with regulatory guidelines (see below at question 7.1).

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Clause 7 of the ABPI Code provides that any comparison made between products must be accurate, fair, balanced, objective, unambiguous, based on an up-to-date evaluation of all the evidence and reflect the evidence clearly. Moreover, comparisons are only permitted in promotional material provided that: they are not misleading; they compare medicines advertised for the same needs or intended for the same purposes; no confusion is created between the medicine advertised and that of a competitor; there is no denigration of a competitor's name or trademarks; no unfair advantage is taken of the competitor's name or trademarks; and the products are not presented as imitations or replicas of a competitor's products. Disparaging references to other products are prohibited (Clause 8 of the ABPI Code).

Advertising material referencing a competitor's product which has not been authorised in the United Kingdom may be characterised as promoting an unlicensed medicine contrary to section 167 of the Regulations and Clause 3 of the ABPI Code.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The distribution of conference proceedings, abstract booklets, meeting reports or slide sets following a scientific congress or conference may constitute promotion depending on the circumstances and the content of such information. To the extent that such information relates to a medicinal product, the provision of such materials on an unsolicited basis may constitute a promotional activity and, therefore, the general requirements regarding promotional materials should be complied with.

Reprints of articles in journals that have not been refereed must not be provided unless in response to a request. Placing documents on exhibition stands amounts to an invitation to take such materials, i.e. it solicits the request. Providing an unsolicited reprint of an article about a medicine constitutes promotion of that medicine and it should be accompanied by prescribing information (Supplementary Information to Clause 10.1 of the ABPI Code).

All material relating to medicines and their uses, whether promotional or not, that is sponsored by a pharmaceutical company, must identify that fact sufficiently and prominently so that the reader or recipient is aware of the position from the outset (Clause 9.10 of the ABPI Code).

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

While there is no specific reference to such advertisements in the Regulations, they are considered unacceptable by Clause 9 of the ABPI Code.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

The holder of the MA for Product A may be able to rely upon the approved use of Product B with Product A in Product A's SmPC provided, as mentioned above, that the claims are consistent with the information in the SmPC and any additional information on this aspect meets the various other requirements of the Directive, such as being presented objectively, faithfully and in such a way as to allow independent verification, and not being exaggerated, misleading or inaccurate. The position is, however, less clear for the holder of the MA of Product B who will, in principle, not be able to make any claims that are inconsistent with Product B's SmPC as this would likely be considered as off-label promotion.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Under section 298 of the Regulations, free samples are permitted, provided certain conditions are met. In particular, samples must only be provided to persons qualified to prescribe medicinal products in order for them to acquire experience in dealing with the product. Samples must not be provided to other relevant decision makers.

Samples must be supplied on an exceptional basis only, and in response to a written, signed and dated request from the receiving healthcare professional. The Regulations require that a "limited number" of samples be provided – the ABPI Code clarifies that this means that no more than four samples of a new medicinal product may be supplied in any one year to any one recipient.

Samples must be no larger than the smallest presentation available for sale, the supplier must maintain an adequate system of control and accountability, and no samples of controlled products may be supplied.

The ABPI Code imposes further restraints in relation to samples, including:

- Samples of a new medicinal product may be provided for no longer than two years after the healthcare professional first requests that sample (although this does not prohibit the provision of samples of new extensions of existing products).
- Samples must be marked with wording indicating that they are free medical samples and are not for resale.
- A copy of the SmPC must accompany samples.
- Samples distributed by medical representatives must be handed directly to healthcare professionals, or a person authorised to receive them on their behalf.

Samples must not be provided as an inducement to prescribe or supply any medicine, or for the sole purpose of treating patients.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Section 300 of the Regulations provides that no gift, pecuniary advantage or other benefit may be provided to healthcare professionals in connection with the promotion of medicinal products unless it is inexpensive and relevant to the practice of medicine or pharmacy.

The ABPI Code goes beyond the limitations established in the Regulations and prohibits the supply, offer or promise of any gift, pecuniary advantage or benefit to administrative staff as well as members of the health professions in connection with the promotion of medicines (Clause 18.1). These provisions exclude nearly all promotional aids (non-monetary gifts made for a promotional purpose) including many of the items distributed traditionally by companies, such as coffee mugs, stationery, computer accessories, calendars, toys or puzzles for children, together with items relevant to the practice of medicine or pharmacy such as surgical gloves, tongue depressors or nail brushes (Supplementary Information to Clause 18.1). The only promotional aids expressly permitted are: inexpensive DVDs or memory sticks, etc. which bear educational or promotional material (which is compliant with the Code); and inexpensive notebooks, pens and pencils for use by healthcare professionals and other relevant decision makers attending scientific meetings, conferences and promotional meetings organised by the company. In the case of materials for use at scientific meetings, such promotional aids must not bear the name or any information about any medicine, but may bear the name of the company providing them; however, if such items are included in conference bags provided at third-party organised conferences, they should not include the company name or the name of any medicine or any information about medicines. The total cost to the donor company of all such items provided to an attendee must not exceed £6, excluding VAT. The perceived value to the recipient must be similar.

Donations of money to healthcare professionals are not permitted, although donations to reputable charities in return for their attendance at meetings may be acceptable provided that any associated action required of the healthcare professional is not inappropriate (e.g. the offer of a donation to charity in return for granting interviews with medical representatives is prohibited). The use of competitions, quizzes and suchlike, and the giving of prizes, are unacceptable methods of promotion.

Section 303 of the Regulations provides that any breach of the rules on the supply of free samples or the solicitation or acceptance of gifts, benefits or hospitality in breach of the Regulations is subject to an unlimited fine and/or where an individual is found guilty of an offence, a period of up to two years' imprisonment. In addition, the National Health Service (NHS) has published general Guidelines on Commercial Sponsorship, setting out ethical standards that all healthcare professionals must observe. For example, NHS staff and contractors must refuse to accept gifts, benefits, hospitality or sponsorship of any kind that might reasonably be seen to compromise their personal judgment or integrity; gifts, benefits and sponsorships must be declared in a register.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

The provision of medical and educational goods and services (MEGS) in the form of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research are only allowed where they: comply with the rules on MEGS for healthcare professionals (see question 4.4, Clause 19 of the ABPI Code) or are made for the purpose of supporting research; they are documented and kept on record by the company; and they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Alternatively, the ABPI Code confirms that package deals, defined as commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, are acceptable (supplementary information to Clause 18.1 of the Code). The Code specifically refers to apparatus for administration, the provision of training on its use or the services of a nurse to administer it, as potential benefits which may be provided as a package deal. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine concerned. New supplementary

information added to the 2019 version of the ABPI Code has clarified that companies may provide genetic testing and other biomarkers/specific testing in relation to the rational use of its medicines and that, where use of a medicine requires specific testing prior to prescription, companies can arrange to provide such testing as a package deal even where the outcome of the testing does not support the use of the medicine in some of those tested.

In addition, the Department of Health encourages "joint working" between the NHS and the pharmaceutical industry where, for the benefit of patients, there is a pooling of skills, experience and/or resources in ways compatible with the ABPI Code (Clause 20). A formal written agreement must be in place for all working projects, and an executive summary of the agreement must be made public before the arrangements are implemented.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

MEGS can be provided where the gift or donation is intended to enhance patient care or to benefit the NHS and maintain patient care (Clause 19 of the ABPI Code). However, such a gift or donation must not be offered as an inducement to an individual prescriber or group of prescribers to prescribe or use any particular medicine. MEGS may bear the company name, but must not bear the name of any medicine.

The ABPI Code also contains detailed guidelines on the provision of MEGS to the NHS. For example, the recipient of any services must be provided with a written protocol setting out the details of the arrangement and, while a company may sponsor a nurse, the nurse must not be used to promoting the company's products. In addition, companies are recommended to inform relevant parties (e.g. NHS Trusts, primary care organisations) of their activities, particularly where the provision of MEGS would have budgetary implications for the parties involved.

The free provision of MEGS to doctors (or other persons qualified to prescribe or supply relevant medicinal products) which provide a personal benefit to them, constitutes an inducement to prescribe. The provision of MEGS must, therefore, be kept entirely separate from promotional activities, and this principle should be reinforced in the training of sales representatives. Prescribers must not, for example, be selected as potential recipients of an offer of MEGS on the basis of their prescribing habits.

Where MEGS improve awareness of a particular disease or assist in diagnosis, this may expand the overall market for relevant treatments without promoting any particular medicine. The ABPI Code confirms that such market extension activities will be acceptable if carried out in a manner compatible with the ABPI Code. However, if the provision of such services leads, or appears to lead, to a change in prescribing habits, there is a risk that the PMCPA will draw an adverse conclusion about the company's and the prescriber's motives, in the absence of clear evidence to the contrary.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Both the Regulations and the ABPI Code state that measures or trade practices relating to prices, margins and discounts are permitted, provided that these are of a type that was in regular use by a significant proportion of the pharmaceutical industry in the UK on 1 January 1993. No official guidance is available on what arrangements would qualify, although the MHRA Blue Guide states: "these are primarily financial terms and normally cover cash discounts or equivalent business discount schemes on purchases of medicinal products, including volume discounts and similar offers such as '14 for the price of 12', provided they are clearly identified and invoiced."

In the case of over-the-counter medicines, while multiple purchase promotions for consumers are not illegal, the MHRA strongly discourages – and closely monitors – offers related to analgesics because of the risk of overdose.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

While an offer of benefit contingent upon the purchase of medicinal products is not permitted, package deals (as described in this question) are acceptable under the ABPI Code. The key criteria provided by the Code are that the transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

The 2014 Pharmaceutical Price Regulation Scheme (PPRS) described patient access schemes (PAS) as schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Care Excellence) in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. PAS are categorised as either simple discount schemes or complex schemes. Simple discount schemes are the preferred model because they place the least burden on the NHS and manufacturers. Complex schemes include all other types of PAS, including arrangements involving rebates, stock supplied at zero cost, dose capping, and outcome-based schemes. Complex schemes are appropriate in exceptional circumstances only, and are unlikely to be suitable for a medicine widely used in primary care.

While the PPRS has, from 1 January 2019, been replaced by the Voluntary Pricing and Access Scheme (VPAS), this confirms that PAS extant as at 31 December 2018, shall be maintained in accordance with their terms. However, the VPAS states that future schemes will be subject to a framework to be published by NHS England, which will offer a similar approach to simple confidential discounts and to published complex PAS. The framework has not yet been published.

The ABPI Code confirms that PAS are acceptable in principle, but they must be carried out in conformity with the Code.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Companies may sponsor Continuing Medical Education (CME) programmes for healthcare professionals, but any such support must be non-promotional and must comply with the rules of the responsible medical royal college, faculty, specialist association or trade body. Most of the medical royal colleges and faculties have formal CME schemes, with accreditation and approval systems that consider the quality of proposed CME activities. An application should be made to the relevant royal college for accreditation of a meeting as CME.

The fact that a meeting or course is approved for CME does not mean that the arrangements are automatically acceptable under the ABPI Code, and company involvement must be reviewed to ensure that it complies with the Code, including in relation to the hospitality provided. A company may provide proposals to CME organisers for programme content, speaker and venue selection. In addition, subject to obtaining the agreement of the event organiser, a company may make available information about its products. A company may pay registration fees for healthcare professionals to attend a CME event and, subject to the restrictions outlined in section 5 below, may also provide travel and subsistence expenses associated with attendance. Healthcare professionals may not, however, be paid an honorarium merely for attendance. There is generally no bar to the presence of sales representatives at a CME event.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The Bribery Act 2010 which came into effect in July 2011 applies to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations.

The Act created two primary offences, bribing and receiving a bribe and introduced two new offences of bribing a foreign public official and of failing to prevent bribery. The latter is of particular concern to pharmaceutical companies as it establishes a strict liability regime, under which companies may be liable unless they can show that they had adequate procedures in place to prevent the offending activity. This means that the pharmaceutical company's own code of ethics or compliance and its implementation have now the dual role of achieving compliance with the applicable laws and codes and contributing to its "adequate procedures" defence.

The Ministry of Justice and the Serious Fraud Office (SFO) have issued guidelines on what conduct would or would not be likely to be prosecuted. However, this guidance should be read with caution by the pharmaceutical industry as its activities are guarded by a different set of ethics than other industries dealing with less regulated products. For example, the Ministry of Justice guidance considers taking foreign clients to a football match with the purpose of cementing good relations as a permitted hospitality, whereas taking healthcare professionals to such events would constitute a breach of the GMC Good Medical Practice Code and the ABPI Code. Such activity would constitute improper performance of a relevant function and therefore a breach of the Act.

In addition, the territorial reach of the Act is extensive and applies beyond activities taking place in the UK. Pharmaceutical companies, wherever they are incorporated, may be liable for acts of bribery if such acts or omissions occur in the UK. If the same acts or omissions occur outside the UK, then the UK courts will have jurisdiction over companies incorporated in the UK.

There is a Memorandum of Understanding between the ABPI, the PMCPA and the SFO dealing with the overlap of responsibilities arising from the interactions between pharmaceutical companies, healthcare professionals and other stakeholders and in particular, those activities covered by the ABPI Code and the Bribery Act. Although both PMCPA and SFO deal with complaints whatever their source, the SFO focus is on dealing with complaints that are not covered by the ABPI Code or other self-regulatory authorities and which meet its criteria of serious fraud.

An additional concern linked with the Bribery Act arises from the Procurement Directive 2004/18/EC, which provides for a sanction of debarment from public procurement to any candidate who has been convicted of an offence, of which the contracting authority is aware. While Member States were able to include a derogation in national legislation (allowing for the right to override this exclusion where it was in the general interest), there is no such derogation in the UK. The UK government has indicated that debarment from public procurement is discretionary where a company is convicted of failing to prevent bribery by an associated person. However, debarment is mandatory if a company is convicted of active bribery, including bribery of a foreign public official.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

This is governed by section 300 of the Regulations, which states that hospitality at meetings or events, whether held for promotional or purely professional or scientific purposes, must be strictly limited to the main purpose or objective of the event, and must only be provided or offered to healthcare professionals. Hospitality is stated to include sponsorship of attendance at the meeting or event, and also the payment of travelling or accommodation expenses.

Clause 22 of the ABPI Code also covers hospitality provided to members of the health professions and other relevant decision makers. Such hospitality may be provided only in association with scientific meetings, promotional meetings, scientific congresses and other such meetings and training. The Supplementary Information to Clause 22 states that spouses and other accompanying persons may not attend the meetings or receive any associated hospitality unless they are also healthcare professionals or other relevant decision makers. Administrative staff may be invited to meetings where this is appropriate.

Clause 22.2 of the ABPI Code sets a threshold for the cost of a meal (including drinks) provided by way of subsistence at £75 per person, excluding VAT and gratuities. However, the Supplementary Information

to Clause 22.2 states that the maximum of £75 is appropriate only in very exceptional circumstances, such as a dinner at a residential meeting for senior consultants or a dinner at a learned society conference with substantial educational content. The cost should normally be well below this figure.

The rules in relation to hospitality apply to any meeting attended by UK healthcare professionals, whether such meeting takes place in the UK or overseas. However, the maximum of £75 for meals and subsistence does not apply when a meeting is held outside the UK in a country where the national association is a member of the EFPIA and therefore covered by EFPIA Codes. In such circumstances, the limits in the host country code of conduct will apply.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Clause 22 of the ABPI Code allows the payment of reasonable travel costs, accommodation and genuine registration fees by a company to enable a delegate to attend a scientific meeting, although the payment of such expenses in relation to persons accompanying the delegate is not permitted. Companies should only offer or provide economy air travel to delegates, although delegates may organise and pay for the genuine difference between economy travel and business class or first class. Further, if the flight is for more than six hours, premium economy flights are permitted. The payment of compensation to healthcare professionals simply for attending a meeting is not permitted, although reasonable honoraria and reimbursement of out-of-pocket expenses may be paid to speakers, advisory board members and providers of other professional services.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Where a company has sponsored a meeting, it is responsible for ensuring that all the arrangements (meeting content and hospitality) comply with the ABPI Code. Even where a company has provided funding to an independent third-party organisation for purposes including the holding of a meeting, but has no control over the arrangements of the meeting or its content, it would be prudent for the company to include requirements for Code compliance in its contract with the third-party organisation.

Where a company sponsors an individual doctor to attend a meeting organised by a third party, the company will be responsible for ensuring that the sponsorship arrangements are consistent with the ABPI Code. A pharmaceutical company is not, in principle, responsible for the content of a meeting organised by an independent third party if the company has had no involvement in or influence over such content and can demonstrate that this is the case.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

It is possible to pay healthcare professionals and other relevant decision-makers to provide genuine consultancy or other services such as speaking at and chairing meetings, involvement in trials, studies and training, and participation in advisory board meetings or market research. However, Clause 23 of the ABPI Code states that a written contract should be agreed before the services commence and a legitimate need for the services must be identified in advance. The number of healthcare professionals involved in such activities must be limited to that necessary to achieve the identified need, and criteria for selecting the healthcare professionals should be directly related to the specified purpose. Recruitment of healthcare professionals should not amount to an inducement to prescribe, and any compensation provided should reflect the fair market value of the service provided. The contracts with healthcare professionals should require them to declare these consultancy arrangements when writing or speaking about matters relating to the agreement or the company. Pharmaceutical companies must make publicly available details of the fees paid to consultants in the UK. From 2015 onwards, the information that must be disclosed is the total amount paid in a calendar year to each consultant who has provided services. The names of the consultants must be disclosed, where consent is given, except in relation to payments for R&D work, where disclosure should be on an aggregate basis.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

A pharmaceutical company may pay compensation to healthcare professionals or institutions conducting non-interventional post-marketing experience or surveillance programmes. Clause 13 of the ABPI Code provides that all prospective studies that involve the collection of patient data must be conducted for a scientific purpose and must not be used as a mechanism for promoting the company's products. Each study must be conducted pursuant to a written protocol, and a written contract should be put in place between the healthcare professionals and/or the institutes at which the study takes place, and the pharmaceutical company sponsoring the study. Ethics committee approvals may be required.

Institutions and investigators must be selected based on their experience or ability to meet the enrolment requirements, and must adhere to the principles of good clinical practice. A healthcare professional's or institution's history of, or potential for, purchasing or prescribing company products may not be taken into account in the selection. Remuneration may be paid on a per patient basis, but must be reasonable and reflect the fair market value of the work.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

It is acceptable to enter into agreements with healthcare professionals for *bona fide* consulting services, including market research activities, but such activities may not be used as a platform for disguised promotion. The name of the company does not need to be revealed in market research material; it is sufficient to state that it is sponsored by a pharmaceutical company. Appropriate compensation may be paid to respondents for their time; however, inducements that could influence respondents' opinions or behaviour must not be offered. The limitations imposed by Clause 23 of the ABPI Code (see question 5.4) do not apply where market research is limited (e.g. one-off telephone interviews or mailings), as long as the consultant is not consulted in a recurring manner, and that the remuneration is minimal.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Pharmacy and general sale list medicines may be advertised to the general public, provided the advertisement encourages the rational use of the product by presenting it objectively and without exaggerating its properties, and is not misleading. Sections 280 to 293 of the Regulations set out additional restrictions on advertising aimed at the general public. In particular, the advertisement must not:

- lead to the use of a medicinal product for the purpose of inducing an abortion;
- relate to medicinal products that contain narcotic or psychotropic substances;
- state, or imply that a medical consultation or surgical operation is unnecessary;
- offer to provide a diagnosis or suggest a treatment by post or by means of electronic communication;
- by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- suggest that the effects of taking a medicinal product are guaranteed, are better than or equivalent to those of another identifiable treatment or medicinal product, or are not accompanied by any adverse reactions;
- use in terms that are misleading or likely to cause alarm, pictorial representations of changes in the human body caused by disease or injury, or the action of the medicinal products on the human body;
- refer in terms that are misleading and likely to cause alarm, to claims of recovery;
- suggest that the health of a person who is not suffering from any disease or injury could be enhanced by taking the medicinal product, or that the health of a person could be affected by not taking the medicinal product;
- suggest that it is a food, cosmetic or other consumer product (and is not, therefore, a medicinal product);
- suggest that a medicinal product's safety or efficacy is due to the fact that it is natural;
- refer to recommendations by scientists, healthcare professionals or celebrities; and/or
- be directed principally at children.

An advertisement relating to a medicinal product must be presented in such a way that it is clear that it is an advertisement, and so that the product is clearly identified as a medicinal product. The advertisement must include: the name of the medicinal product; the common name of the active ingredient; any information necessary for the correct use of the medicinal product; and a clear invitation to read the instructions carefully.

Further guidance on the interpretation of these provisions is contained in the PAGB Code.

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Section 284 of the Regulations prohibits advertisements that are likely to lead to the use of POMs.

However, Clause 26.2 of the ABPI Code allows the provision of non-promotional information regarding POMs to the public in response to a direct enquiry from an individual and in certain other circumstances (including enquiries from journalists, dissemination of information via press conferences, press announcements, television and radio reports, public relations activities, etc.). Such information must be factual, balanced and must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a particular POM.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Disease awareness campaigns are permitted (Annex 7 to the Blue Guide, Clause 26.2 of the ABPI Code). It is important that the purpose of the campaign is to increase awareness of a disease and to provide health education information on that disease and its management. While it may involve a discussion of treatment options, it must not promote the use of a particular medicinal product. Disease awareness campaigns where there is only one treatment option, or only one medicine in a particular class, require particular care. The provision of advice on personal medical matters to individual members of the public is not permitted.

### 6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Both options are possible, provided the information is of genuine scientific interest and not of a promotional tone. It must not encourage members of the public to ask their doctor to prescribe a particular product. Use of the brand name should be kept to the minimum. Press releases must be certified as compliant with the ABPI Code before being issued.

### 6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Companies may provide appropriate information on both their existing medicines and those not yet marketed to the UK business and financial press in line with their obligation to inform shareholders, the Stock Exchange, etc., of developments that may be material to their UK share price. Business press releases and corporate brochures should identify the commercial importance of the information and should be factual and balanced.

Clause 14 of the ABPI Code requires companies to take account of the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the ABPI Code. Corporate information should always be examined to ensure that it does not contravene the ABPI Code or the relevant statutory requirements, and is not subject to the certification requirements.

### 6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

Clause 27 of the ABPI Code states that pharmaceutical companies may interact with patient organisations or user organisations to support their work. However, such involvement must be transparent

and all arrangements must comply with the ABPI Code. The limitations on the hospitality to be provided to healthcare professionals (see section 5) are also applicable.

Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, including funding, in relation to every significant activity or ongoing relationship. Where patient organisations are engaged to provide any type of services to companies, such services must be for the purpose of supporting healthcare or research, and similar restrictions apply as in relation to the engagement of healthcare professionals to provide expert services (e.g. there must be a legitimate need for the services, compensation must be reasonable, etc. – see question 5.5). No company may require that it be the sole funder of a particular group or programme. Material relating to working with patient organisations must be certified in advance by two persons on behalf of the company (see question 1.3).

There are other codes and guidelines applicable to specific patient organisations, such as the National Voices and ABPI Working Together, Delivering for Patients guidelines. In addition, patient organisations are likely to be covered by the rules of the Charity Commission (the regulator and registrar for charities in England and Wales), as well as their own constitutions.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Companies may provide healthcare professionals with items intended to be passed on to patients provided they are part of a patient support programme, the details of which must be appropriately documented and certified in advance (Clause 18.2). Such items should be "inexpensive" (defined as costing the donor company no more than £6, excluding VAT, and the perceived value to the healthcare professional and the patient must be similar).

Permitted patient support items must directly benefit patient care. They may bear the name of the company providing them. They must not be given to administrative staff unless they are to be passed on to a healthcare professional. Although such items may not be given out from exhibition stands, they may be exhibited and demonstrated on stands and requests for them accepted for later delivery. Examples of items which might be acceptable are a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise.

In limited circumstances, items may be made available for the use of healthcare professionals even though they are not to be passed on to patients for them to keep, provided that the items have been appropriately documented and certified. This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a healthcare professional. For example, an inhalation device (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Prior to the implementation of the Clinical Trials Regulation 536/2014/EU which is currently due to come into operation in 2019, disclosure obligations in the UK are dealt with by the Medicines for Human Use (Clinical Trials) Regulations 2004. These Regulations do not contain specific requirements regarding publication of clinical trial data.

However, Clause 13.1 of the ABPI Code requires companies to disclose details of clinical trials in accordance with the IFPMA/EFPIA/PhRMA/JPMA's Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature. These guidelines include a requirement that current and future trials are registered within 21 days of enrolling the first patient, and that results are published within one year of the marketing authorisation or one year from the completion for marketed products. Companies should include information as to where details of their clinical trials can be found on the home page of their website. In addition, companies must publish summary details and results of non-interventional studies in the same way as for clinical trials.

The ABPI has published a clinical trial disclosure toolkit with good practice guidelines, disclosure checklists and template standard operating procedures for pharmaceutical companies.

The PMCPA has found companies in breach of the ABPI Code where information and data from clinical trials have not been disclosed in accordance with the relevant requirements. One complaint led to 25 cases covering 35 products from 21 companies. Seven of the 25 cases were found to be in breach of the Code.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

The Regulations do not include a requirement for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations. In the UK, these requirements arise from the self-regulatory system, as described below.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Clause 24 of the ABPI Code incorporates the requirements of the EFPIA Disclosure Code without any significant variation. Companies must document and publicly disclose certain transfers of value made directly or indirectly to healthcare professionals and healthcare organisations located in Europe. The transfers of value covered are: (i) joint working; (ii) donations, grants and benefits in kind provided to institutions, organisations and associations; (iii) contracts between companies and institutions, organisations and associations; (iv) sponsorship of attendance by healthcare professionals

and other relevant decision-makers at meetings; (v) fees and expenses paid to healthcare professionals and other relevant decision makers, or to their employers on their behalf; and (vi) contributions towards the costs of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include sponsorship of healthcare professionals by way of registration fees and accommodation and travel. The requirement to disclose transfers of value arises independently of whether the company has obtained a marketing authorisation for a medicinal product.

Disclosure of transfers of value to UK health professionals and health organisations by ABPI members and non-members who have agreed to comply with the Code and their affiliates, must be made on the central platform for disclosure in the UK. The use of the central platform is mandatory for ABPI members and non-members who have agreed to comply with the Code, but other companies may also use it. Companies are free to provide additional disclosure by providing the information on their own company websites. A new 2019 template which companies can use to comply with the disclosure obligations is available to download from the PMCPA's website.

Disclosure must be made annually, in the first six months after the end of the calendar year in which the transfers were made, and must remain in the public domain for at least three years from the time of disclosure.

Transfers of value to healthcare professionals can be aggregated on a category-by-category basis, but payments to healthcare organisations are required to be disclosed on a per activity basis. The term "healthcare professional" in relation to disclosure of transfers of value also includes any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional.

Companies must publish a summary of the methodologies used to prepare the disclosure and identify each category of transfer of value to include a description of the recognition methodologies applied and the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of transfers of value.

### 7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

If a healthcare professional, who has received transfers of value from a company, refuses to agree to the disclosure of one or more of such transfers of value, the company will need to report such transfers on an aggregate basis (supplementary information to Clause 24.9 of the ABPI Code). This will include situations where the healthcare professional declines to give consent or decides to withdraw consent under data protection legislation. The ABPI has confirmed that they cannot, and will not, mandate that their members only work with healthcare professionals who consent to disclosure. It is up to the companies to decide individually which healthcare professionals they will work with and the terms of those arrangements.

## 8 The Internet

### 8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The same rules apply to digital communications as to other forms of advertising. Promotional material directed to a UK audience which is provided on the internet is, therefore, subject to the Regulations and the ABPI Code. However, the regulators are only able to enforce the requirements against entities with a presence in the jurisdiction. Clause 28 of the ABPI Code indicates action will be taken where the advertisement has been placed on the internet by, or with the authority of, a UK company or an affiliate of a UK company, and makes reference to the availability or use of a medicine in the UK.

The MHRA Blue Guide states that the UK rules will apply to "material posted on UK websites and/or aimed at the UK audience". Where companies include links from their UK site to their websites serving other countries, this should be made clear to UK users – users should not need to access non-UK sites to obtain basic information about the company's products, such as package leaflets, summaries of product characteristics, public assessment reports and other non-promotional material.

The MHRA has developed specific guidance for consumer websites offering medicinal treatment services. This states that, as a general principle, online services such as online clinics or pharmacies may promote the service they provide. This includes providing information on relevant conditions and their management, and may include a balanced overview of the range of therapeutic options. However, any such material should not draw attention to specific POMs.

The MHRA operates a targeted approach to action on clinics and other services offering treatments involving *botulinum toxin* products and other POMs. It focuses on clinic websites, and aims to ensure that customers seeking general information about a clinic or potential treatments are not presented with advertising for POMs. Individuals with concerns about advertising on websites can also complain to the Advertising Standards Authority, which has dealt with a number of cases relating to the advertising of medicines, particularly *botulinum toxin* products and homeopathic medicines.

### 8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

The MHRA Blue Guide states that advertisements for POMs are acceptable only on websites whose nature and content are directed at healthcare professionals, and as such, any sections of a website aimed at healthcare professionals should ideally be access-restricted. If no restriction is applied, the sections for consumers and healthcare professionals should be clearly separated and clearly marked for the target audience. Open access websites should provide non-promotional information in public areas so that individuals do not need to access sections for healthcare professionals unless they choose to seek further detailed information. Actively directing members of the public to advertising material for POMs is likely to be contrary to the Regulations.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Although the supplementary information to Clause 28.6 of the ABPI Code states that sites linked via company sites are not necessarily covered by the ABPI Code, PMCPA guidance on digital communications states that any website chosen by a company to link to from its website should stand up to scrutiny. Companies should be confident about the choice of linked sites and that these do not promote POMs to the public. For example, referring healthcare professionals or patients to a website giving information about an unlicensed indication may be viewed as promoting that unlicensed indication. It is preferable to link to the homepage. It should be made clear when a user is leaving any of the company's sites, sites sponsored by the company or is being directed to a site which is not that of the company.

If an independent website provides a link to a company website, the company will only be responsible for any breach of the ABPI Code that might arise as a result of the linkage (e.g. linking a site accessible by the general public to a site for healthcare professionals) if the link was established with its knowledge and consent.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

The MHRA Blue Guide states that companies may include the following information on a website aimed at the public:

- Information on disease awareness and health education campaigns (see question 6.3).
- Patient information leaflets (PILs), summaries of product characteristics (SmPCs) and public assessment reports (PARs) for their POM products.
- Other non-promotional reference information about the product that fairly reflects the current body of evidence about the product and its benefit risk profile (such as the registration studies used for marketing authorisation applications and variations and any other published or unpublished studies including those referred to in the SmPC, PIL, PAR or available on clinical trial databases).

Where a company includes links from its UK site to parts of its website serving other countries, UK users should be made aware that they have chosen to access material aimed at users in other countries. UK users should not need to access non-UK parts of the website to obtain basic information about the company's products, and it is good practice for each page of the website to include a statement that makes clear the intended audience.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

In March 2016, the PMCPA published a revised Guidance on Digital Communications. The Guide addresses cross-border privacy issues, as well as providing commentary on the use of email by pharmaceutical companies and revised advice on how companies can make the best use of digital communication tools such as Twitter, Facebook, Pinterest and Wikipedia, whilst complying with the requirements of the ABPI Code. The Guide highlights that the use of social media to promote POMs is likely to be problematic, as it may not be possible to limit the audience to ensure that members of the public are not able to access the materials. PMCPA cases have found that the dissemination of product information via Facebook and Twitter amounted to promotion.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

The ABPI Code of Practice of 2016 was amended in December 2018 and the updated Code came into operation on 1 January 2019. The changes to the Code were mainly based on the feedback from the pharmaceutical companies and other stakeholders and the necessary regular updating. The Code provides a transition period until 30 April 2019 to comply with the newly introduced provisions. In addition to the changes to the Code, the ABPI has provided a new disclosure template to be used by member companies to submit 2018 data to Disclosure UK.

The main changes in the 2019 Code relate to clarifications on the definition of promotion, Early Access to Medicines Schemes, conditional licensing, risk management plans, the scope of the exception for "package deals", how to identify a budgetary implication that would justify the advance notification of new products or product changes to healthcare organisations, the use of links for prescribing information, certification requirements, small amendments to the Constitution and Procedure and a new introduction setting out the principles and overview of self-regulation.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

The MHRA Medicines Industry Liaison Group will continue to work in 2019 with the ABPI and other interested parties to develop proposals to extend the simplified information requirements for advertising to the prescription medicines sector. Any proposals will need to balance burden reduction for industry with the need for healthcare professionals to have ready access to the information they need to be able to use products safely.

An Expert Working Group (EWG) of the UK's Commission on Human Medicines (CHM) has met this year at the MHRA to begin a review of the benefits and risks of opioid medicines, including dependence and addiction.

From a self-regulatory perspective, the PMCPA has announced that they are working on changes on its website to facilitate searches with a new functionality to search by relevant Code year and clause and with easier access to questions and answers notes.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

In line with the previous years, the level of advertising complaints received by the MHRA in 2018 continues to decrease; 158 complaints compared with 369 in 2009. As in 2017, all complaints were concluded through voluntary agreement with the companies concerned, without recourse to statutory procedures. There were no complaints of misleading advertising sufficiently serious to require the issue of a corrective statement and no complaints upheld by the

PMCPA for vetted advertising. In 2018, as in previous years, the complaints that the MHRA Advertising unit dealt with in association with the MHRA Enforcement Group related mainly to advertising of POMs to the public (90% of the complaints in 2018), including by clinics offering treatments for lines and wrinkles and internet pharmacies promoting POMs.

The MHRA Enforcement Group continued its actions to stop the illegal sale of medicines and medical devices. "Operation Pangea XI" continued with the seizure of fake medicines, 123 websites shut down and there was a removal of 535 online adverts. Following a three-year investigation, a Guernsey-based company owner has been sentenced to a total of 15 months in prison, while three individuals were sentenced at a London court for their involvement in the illegal supply of potentially dangerous POMs.

The number of complaints made under the self-regulatory system remained broadly constant between 2017 and 2018. Recurrent errors arising from 2018 cases were the lack of notification to MHRA and PMCPA of the final company signatories, the provision of material about unlicensed medicines proactively disseminated, the use of social media and company websites by companies, the links and version control to prescribing information and the use of the black triangle.

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Silvia Valverde is a senior lawyer at the firm's Food, Drug and Medical Device practice and the Professional Support Lawyer of the pharma group in Arnold & Porter's London office.

She has extensive experience advising life sciences companies on EU and UK pharmaceutical legislation covering a broad range of issues that arise throughout the life cycle of the product, including research, manufacturing, licensing, supply, and promotion. She combines her pharma regulatory experience with her practice on compliance and enforcement matters to assist life sciences companies in conducting internal investigations, and implementing compliance programmes, including risk assessments, remediation plans, enhancement of policies, and training.

Ms. Valverde's dual experience is in pharmaceutical regulatory and compliance, and her secondments in-house to multi-national pharmaceutical clients, gives her a practical perspective when advising on complex cross-border issues. She is used to working in liaison with legal, regulatory, compliance, and business teams in a large number of markets.

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Adela Williams is a Partner in Arnold & Porter's London office. She is also medically qualified.

Her practice focuses on the regulation of medicinal products, medical devices, foods and cosmetics in the UK and at EU level, particularly in relation to clinical trials, marketing authorisations and advertising and promotion issues, including legal proceedings arising from the decisions of regulatory bodies. She advises clients in relation to compliance issues and proceedings before the Prescription Medicines Code of Practice Authority and its Appeal Board arising from alleged breaches of the ABPI Code of Practice on promotion of medicines and related activities.

She also advises clients in relation to the pricing and reimbursement of medicines and medical products. This area of her practice includes both statutory and voluntary pricing regimes (VPAS) in the UK, the application of the Drug Tariff and all stages of health technology appraisals by the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium, and the All Wales Medicines Strategy Group. She frequently represents clients at NICE appeal hearings and has acted on behalf of the manufacturer company in two of the three applications for judicial review brought against NICE in the Administrative Court.

She has substantial experience representing pharmaceutical and medical device clients in product liability litigation (unitary actions and group litigation), including claims involving unlicensed medicines in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within the EU and advising on forum and other jurisdictional issues.

Arnold & Porter

Arnold & Porter is an international law firm with nearly 1,000 lawyers in 15 offices in the USA, together with offices in Belgium, China, South Korea, Germany, and the UK.

The EU life sciences team, headed by Ian Dodds-Smith and based in London, has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the life sciences sector.

The team of lawyers specialising in this field in London is complemented by Arnold & Porter's highly regarded pharmaceutical and medical devices regulatory practice headed by Dan Kracov in Washington, D.C., giving a combined team of over 40 lawyers.

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# Finland

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Advertising of medicinal products in Finland is governed by the Medicines Act (395/1987, as amended) and the Medicines Decree (693/1987, as amended).

Also, the Code of Ethics (revised 1 January 2017) ("PIF Code") issued by Pharma Industry Finland ("PIF") contains detailed provisions on the advertising of medicinal products, complementing the statutory legislation. The PIF Code has been drafted and implemented by the representatives of the pharmaceutical industry. All members of PIF (which includes, in practice, most of the major players in the pharmaceutical industry in Finland) have undertaken to comply with the PIF Code and therefore it represents the generally accepted code of conduct of the industry.

On a general level, the Consumer Protection Act (38/1978, as amended), which is applicable to consumer advertising, and the Act on Unfair Business Practices (1061/1978, as amended), which is applicable to business-to-business advertising, may apply to the advertising of medicinal products. With the exceptions of an action based on unfair business practices (see question 1.9 below) and comparative advertising (see question 3.4 below), these general provisions will not be described in more detail below.

### 1.2 How is "advertising" defined?

Advertising of medicinal products is defined as all types of publicity, advertising and promotional activities intended to promote the prescription, supply, purchase or use of medicinal products. This includes, *inter alia*, advertising directed at the general public, advertising directed at persons qualified to prescribe or supply medicinal products, sales promotion and activities of medicinal sales representatives. Also, the distribution of samples shall be considered as advertising of medicinal products.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Pharmaceutical companies must have a scientific service unit responsible for the information distributed on the medicinal products of the company and for the correctness of such information. Under the PIF Code, the scientific service unit must employ at least one physician or pharmacist responsible for the approval of the company's advertising measures before their publication, including events, advertisement gifts and market studies. This person must ensure that the final form of the advertising measure complies with the PIF Code and the legislation on pharmaceuticals advertising.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

No, there are no legal or code requirements for companies to have specific standard operating procedures, although most companies have such in place. In terms of specific personnel, see question 1.3 above for requirements concerning scientific service units.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

There is no mandatory requirement for prior approval of advertisements by the Finnish Medicines Agency ("Fimea") or the PIF. However, a pharmaceutical company may voluntarily request the supervisory body acting under the PIF to inspect an advertisement directed at consumers in advance. Notwithstanding the aforementioned, it is stipulated in the PIF Code that all television and radio advertisements for medicinal products shall be submitted for preliminary inspection to the PIF.

The supervisory body operating under the PIF may, in connection with the preliminary inspection, approve the contemplated radio or television advertisement as such, or with amendments, or reject it.

If material other than the final advertisement is presented, the statement of the supervisory body given in connection with the examination of such unfinished material will not be considered as the supervisory body's final opinion of the finished advertisement. The supervisory body is, however, bound to the opinion given by it on the compliance of the manuscript with the PIF Code. The supervisory body must give the applicant a separate justified decision on the preliminary inspection of the advertisement, indicating the date of the decision. The applicant shall be notified of the decision immediately.

A preliminary advertisement which has been inspected can be shown for a period not exceeding three years from the date of approval.

Concerning advertising measures other than radio or television advertisements, the preliminary inspection may focus on the question of whether the measure in question complies with the PIF Code and whether it would be prohibited through subsequent supervision. The preliminary inspection decision must specify the reasons for which the advertising measure does not comply with the PIF Code.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Fimea may prohibit a company from continuing or repeating advertising that violates the provisions of the Medicines Act and Medicines Decree. FIMEA may also order a company to rectify improper advertising, if considered appropriate due to the safety risk of medicinal products. A conditional fine may support a prohibition or order issued by Fimea.

Fimea's decision to prohibit or rectify improper advertising may be appealed to an Administrative Court and further to the Supreme Administrative Court. The time to appeal is 30 days from the date of service of the decision. Fimea's decision must be complied with unless the appellate court rules otherwise.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

A person that intentionally, or due to negligence, acts in violation of the Medicines Act or Medicines Decree or FIMEA's prohibition or order may be sentenced for a pharmaceutical offence to fines or imprisonment of up to one year. If the act is only due to negligence, the person may be fined for a pharmaceutical infringement. Criminal proceedings are handled by the general courts and initiated by the general prosecutor.

In October 2006, Fimea prohibited a major pharmaceutical company from advertising a medicinal product with material which was not in accordance with the approved summary of product characteristics. Fimea also prohibited such advertising which omits an essential detail for the medical value of the medicinal product or which refers to a clinical trial in a way that misrepresents the conclusions, extent and significance of the trial. The prohibitions were enforced with a conditional fine in the amount of EUR 2 million.

It is not common for competitors to take direct action through courts for advertisement infringements but it happens from time to time that a pharmaceutical company files a complaint with Fimea against a competitor (which is not a member of PIF) and requests that it takes action and prohibits the advertising of the competitor.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The supervisory bodies acting under the PIF monitor the appropriateness of advertising medicinal products by PIF's member companies and compliance with the PIF Code. A matter may become pending in the supervisory bodies on the bodies' own initiative or based on a complaint. Anyone can lodge a complaint against measures taken by PIF's companies committed to the PIF Code falling within the scope of application of the PIF Code. The sanctions which the supervisory bodies of the PIF may issue for violation against the PIF Code include: an admonition for future reference; a request to abstain from incorrect activity; a processing charge; a compensation payment; a sanction payment (minimum EUR 1,000 and maximum EUR 100,000); and an order to rectify and correct the measures taken. In addition, a company may be ordered to pay liquidated damages (minimum EUR 20,000 and maximum EUR 300,000). The supervisory body may also submit the matter to Fimea for action if, e.g., a company continues its non-complying activity in spite of an admonition, requests to abstain from incorrect advertising or temporarily requests to abstain.

Disagreements between pharmaceutical companies concerning a violation of the PIF Code shall be submitted for examination to the system set forth in the PIF Code before they may be brought to the attention of the relevant authorities. A member company that has bypassed said system can be ordered to pay liquidated damages. Liquidated damages can also be imposed if the company violates a contract made amicably with another pharmaceutical company in relation to the discontinuation of incorrect advertising.

If a case is being examined by the authorities, the supervisory body of the PIF does not issue a decision on it until such proceedings have been finalised. After a final decision by the authorities has been issued, the case can be decided by the supervisory body, considering the dimensions of the decision by the authorities as well as the eventual sanctions imposed. If the examination of the case by the authorities is considerably delayed, the supervisory body of the PIF can, exceptionally, take up the case despite the pending process with the authorities.

Fimea may handle a matter even though it is being assessed or has been decided by the supervisory body of the PIF.

According to the PIF Code, the Inspection Board or the Supervisory Commission can, upon the request of the interested party, at their discretion, impose an EUR 5,000 compensation payment for an unfounded complaint made merely for the purpose of harming the competitor, payable to the company suffering from the complaint to cover the costs incurred for the reply to the unfounded complaint.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Under the Act of Unfair Business Practices, practices that are contrary to good business practices or that are otherwise unfair in relation to other entrepreneurs may not be used in advertising.

Advertising shall also clearly indicate its commercial purpose and the party or the benefit of whom the advertising is carried out. Furthermore, it is prohibited to use in commercial activities such false or misleading expressions regarding their own or another entrepreneur's business activities that are likely to affect the demand or supply of goods or to harm another entrepreneur's business activities.

An action based upon the violation of the provisions of the Act on Unfair Business Practices may be initiated at the Market Court by an entrepreneur who is affected by the violating action or whose activity it may damage; e.g. a competitor. The Market Court may prohibit the continuation of the unfair practice and order suitable rectifying measures. The Market Court may also support a prohibition or rectifying measure order with a conditional fine. Finally, the losing party may be required to reimburse the opposing party's legal costs. A party may appeal a decision by the Market Court to the Supreme Court if the Supreme Court grants leave to appeal.

A competitor that has suffered damages due to the unfair practice of another entrepreneur may also sue for damages at a General Court. Finally, the public prosecutor may bring criminal charges against an entrepreneur that has deliberately, or out of gross negligence, used false or misleading expressions in advertising.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Only medicinal products referred to in the Medicines Act may be advertised or marketed as medicinal products. It is prohibited to market medicinal products lacking market authorisation in Finland.

It is not acceptable, e.g., at training events, to give specific information of non-authorised medicinal products using the contemplated trade name. However, it is acceptable to give objective information of published research results regarding non-authorised medicinal products, by using the generic name.

In case a healthcare professional has obtained information, e.g. at an international training event, of the name of a medicinal product which has not yet been authorised in Finland but will be marketed using the same name, it is acceptable upon request to inform the doctor thereof. The active advertising of such product is prohibited.

The aforementioned prohibition to market medicinal products which do not have a marketing authorisation in Finland applies also at international events arranged in Finland, according to Finnish legislation.

However, general information on a pharmaceutical company and their portfolio as well as research activities and results is not considered to be advertising (in the context of the Finnish medicines regulation) and thus is allowed. In practice, this leaves two possibilities to distribute information about non-authorised products:

1) advertising of the company itself, where the product portfolio can also mention products without marketing authorisation in Finland; and
2) information of a company's product development programmes, without any brand names, but information of the results of research programmes. No therapeutic claims are allowed.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

It is acceptable to provide neutral information of scientific research results concerning unauthorised products and/or off-label information. However, product trade names shall not be used.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

The same rules apply as in question 2.2 above. However, in case the press release is issued by a listed company and based on the statutory information liability of the pharmaceutical companies, such a press release could in certain situations also contain the trade name of the product, as this type of press release is outside the scope of the PIF Code.

When issuing a press release about unauthorised medicines and/or off-label information, the issuer must ensure that such a press release does not contain any elements of advertising whatsoever. The same limitation applies to specialised/scientific media (see above the answer to question 2.1).

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

It is acceptable to provide information on scientific research results for medicinal products which are not yet authorised, only if the healthcare professional has explicitly requested the information; unsolicited distribution of information is, as the main rule, not allowed. Information sent to healthcare professionals upon request may not contain any trade names of unauthorised products and reference shall only be made to the name of the active ingredient. Furthermore, information on the research results shall be presented in a neutral and objective way.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

According to the Medicines Decree, product and price lists are not considered advertising. However, such product and price lists may not contain any claims concerning the medicinal product in question. This rule also applies to products approved by Fimea for named-patient/compassionate use purposes.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

According to Fimea, the offering of a pharmaceutical product without a valid marketing authorisation (or with a pending marketing authorisation) in tender offers is prohibited by virtue of the Medicines Act, unless the tender offer has not been specified to explicitly concern said product.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

It is possible to enter into consultancy agreements with healthcare professionals, for, e.g., market research purposes. It should be noted, however, that such consultancy relationships must fulfil certain criteria set forth in the PIF Code (e.g. a written agreement requirement and that the consultancy fees are on a reasonable level) and that the pharmaceutical company may not engage more healthcare professionals, e.g. in market research, than is reasonably needed.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Advertising of medicinal products to persons qualified to prescribe or supply such products shall include essential information on the medicinal product and its use. In particular, such advertising shall include:

- essential information, in accordance with the summary of product characteristics, on the purpose of use, recommended use, effect and safety of the product;
- legal conditions of supply;
- conditions of reimbursement under the health insurance system, average treatment costs, where possible, and retail prices of different packages; and
- the date when the advertisement was prepared or revised.

All information given in advertising should correspond to the approved summary of product characteristics, be accurate, up-to-date, verifiable and clear enough to enable the reader to form an opinion of the therapeutic value of the product. Quotations, as well as tables and other illustrative matter taken from medicinal journals or scientific research shall be faithfully reproduced and the precise sources indicated.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

As the main rule, an advertisement may not contain any information that is not compliant to its content with the approved SmPC (e.g. off-label information).

However, an advertisement may refer to studies which have not been explicitly mentioned in the SmPC, provided that such studies have been appropriately published, the information is compliant with the SmPC and the reference fulfils other general requirements for advertisements as listed above in question 3.1 and below in question 3.4. Moreover, it is permissible to include the mention of these in the material for the advertising of medicinal products articles which have been accepted for publication in scientific journals, as well as the results of trials or studies submitted to the regulatory authorities in association with marketing authorisation applications. The unpublished study results must meet the same quality criteria applied to published results. Any reference to study results must be associated with explicit information on the trial arrangements (e.g. *in vivo*, *in vitro*, animal testing).

As an exception to the above, reference may also be made to such study results which have not been published, if they can be deemed to have material significance for the medication of patients. New information has material significance if it refers to a serious disease and if there is clear proof that the treatment in question is superior to the earlier treatments.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

The PIF Code requires that pharmaceutical promotion must not contain direct and active recommendations to use the medicine given by scientists, healthcare professionals or celebrities.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There are no numeral requirements to this extent. The PIF Code only stipulates that the comparison between different active ingredients shall be based on scientific evidence.

Furthermore, any research results included in the material for the advertising of medicinal products must have been published in article form in a scientific journal. Moreover, it is permissible to include this in the material for the advertising of medicinal products articles which have been accepted for publication in a scientific journal, as well as trials supplied to the regulatory authorities in association with a marketing authorisation application.

The use of unpublished material, such as abstracts or posters of similar materials which have not been published in scientific journals, is, as a rule, prohibited.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

The Medicines Act stipulates that advertising may not provide a misleading or exaggerated picture of the formula, origin or pharmaceutical significance of a product, or be inappropriate in any other similar way.

In addition, the Unfair Business Practices Act contains general provisions regarding comparative advertising which may be applicable to the advertising of medicinal products.

Furthermore, the PIF Code stipulates that comparisons between different medicinal products, active ingredients, excipients or other characteristics must be accurate and reliable. The graphic comparison and price comparison of the product shall be clearly justifiable. The object in comparison shall be clearly recognisable.

The packages and dosages used in price comparisons shall correspond to each other. When the prices of products are compared, the medicinal products covered by the comparison and their trade names shall be clearly indicated. When using comparisons in advertising, the time of comparison or the date of publication shall be disclosed.

Special weight shall be given in the comparison to the objectivity of advertising and the correctness of information.

There are no explicit rules prohibiting a company from referring to a competitor's product or indication which has not yet been authorised in Finland. However, such information may be considered inessential from the point of view of a Finnish consumer and healthcare professional as the product is not available for sale or prescription in Finland. Consequently, it is possible that comparative advertising of this kind may be considered inappropriate.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Scientific material published by the pharmaceutical industry, e.g. scientific papers and proceedings of congresses, are explicitly excluded from the scope of the advertising provisions of the Medicines Act and Decree, as well as the PIF Code. There are no specific rules on the distribution of scientific material. Distribution of scientific materials is basically permitted as long as it constitutes a genuine exchange of scientific information and is not a hidden sales promotion of a medicinal product.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There are no specific rules on "teaser" advertisements, and basically all advertising directed at healthcare personnel shall fulfil the content requirements described above (see question 3.1). An exception to this basic rule involves "reminder advertising". Reminder advertising means advertising that is intended solely as a reminder of the name of the product. Reminder advertising may contain only the trade name of the product, the name of its active substance and the trademark of the product, as well as the holder of the marketing authorisation, marketer, importer or manufacturer and its company logo. The nature of a reminder advertisement is thus the opposite from that of a teaser advertisement, in the sense that reminder advertisements are used after a product has already become known to remind the target group of the existence of the product. It remains unclear, however, whether the provisions on reminder advertisements could also be a basis for permitting teaser advertisements.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Promotion of a medicinal product must be based on the most recently approved SmPC. Use of Product A in combination with Product B could thus be referred to as part of the promotion of Product A. If Product B is referred to by its trade name, instead of its active ingredient, it is still recommendable to obtain consent for such reference from the marketing authorisation holder of Product B. In case the combination use is not an approved indication of Product B, promotion of Product B for such use could be considered to violate the applicable advertising regulation.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Samples of medicinal products may be distributed only to persons entitled to prescribe and supply them. Samples of prescription drugs can be distributed only to persons entitled to prescribe medicinal products. If the prescription is subject to restriction of supply, the sample can only be given to the doctor entitled to prescribe it. During the two years following the introduction of the medicinal product to the market or the adoption of its reimbursable price, one package of each medicinal product, strength and pharmaceutical form can be given as a free sample to each recipient in one calendar year. The free medicine samples can be distributed for a maximum of two years. However, this does not apply to distribution of free samples of self-care medicinal products.

A sample may be distributed only on the basis of a written, signed and dated request, and pharmaceutical companies must keep records of the free samples given in each calendar year. A sample shall be exactly the same as the smallest package size available on the market. Each sample shall be accompanied by a summary of product characteristics.

Narcotics, including psychotropic substances and substances that mainly affect the central nervous system, must not be distributed as samples.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Under the Medicines Act, sales promotion of medicinal products to healthcare professionals, such as gifts and benefits, must be inexpensive and related to their professional activities. Hospitality at sales promotion events must be reasonable and secondary compared to the purpose of the event.

The PIF Code contains stricter rules on incentives, gifts, advertising gifts and other support measures. Under the Code, it is forbidden to give promotional gifts related to prescription-only medicines. While the distribution of promotional gifts related to the advertising of non-prescription medicines must be reasonable, such gifts must have minor economic significance for the recipient and they must have bearing on their professional operations. Such gifts may not exceed EUR 35 (retail price including VAT). Healthcare professionals must not be offered or otherwise provided with direct or disguised economic incentives, gifts or promotional articles constituting inducements. Making donations or awarding grants to individual healthcare professionals is only permitted for performing so-called investigator-initiated clinical trials with a proper study protocol, which is approved by the regulatory authority and ethics committee and otherwise meets the statutory criteria for clinical trials.

It should also be noted that offering an additional benefit may be considered a bribe if the benefit is significant and may induce the recipient to make such acquisitions that would not otherwise be justifiable for the institution.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Donations to institutions as such are possible. The PIF Code stipulates that donations, grants and benefits offered to institutions, organisations or associations are permitted if their members are healthcare professionals or if they provide healthcare services or engage in research and their purpose is to support healthcare and research. Such donations or grants must not constitute an incentive for, *inter alia*, the recommendation, prescription, purchase or supply of a particular medicinal product. No monetary limits apply for such donations.

Under the PIF Code, a company can engage in sponsorship activity using the company name. However, the use of a product name is not allowed. The PIF Code also contains specific rules on the obligation to disclose economic benefits targeted at healthcare organisations or professionals. The requirements on disclosure of transfers of value set forth in the PIF Code are in line with the requirements of the EFPIA Disclosure Code.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Sales promotion may not be inappropriate or such that it may endanger the trust of the general public that the prescription, use or assignment of medicinal products is independent. Consequently, arrangements where medical or educational goods and services are provided to doctors that could lead to changes in prescribing patterns will most likely be considered inappropriate.

The PIF Code further stipulates that healthcare professionals can be provided with informative and educational material and medicinal supplies under certain conditions if these do not constitute an incentive for, *inter alia*, the recommendation, prescription or sale of a particular medicinal product.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Pharmaceutical companies are not permitted to grant discounts to individual pharmacies, and the wholesale price shall be the same in all pharmacies. The wholesale price shall include all rebates, refunds and other benefits that are granted to a pharmacy. The aforementioned restrictions do not apply to such medicinal products which may be sold in places other than pharmacies, such as nicotine replacements. It is, however, permitted for pharmaceutical companies to grant discounts to welfare and health units, e.g. hospital districts and individual hospital pharmacies.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

There are no explicit rules prohibiting the provision of equipment or services to third-party institutions contingent on the purchase of medicinal products. However, it cannot be ruled out that in some circumstances, such an arrangement may be considered unacceptable, particularly where the arrangement jeopardises the public's trust in the impartiality of prescribing or supplying medicinal products.

Commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as a part of the purchase price are not acceptable as the provision of certain associated benefits (such as administrators) may not constitute an incentive for the purchase of a medicinal product.

As for consumers, it is, as a main rule, forbidden to give the buyer of a non-prescription medicine another product or benefit (giveaways) at the same price.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

The Medicines Act and Medicines Decree do not contain any specific provisions to this extent. According to the PIF Code, the advertising of medicinal products shall follow good practices in order to inspire truth and esteem. It is possible, however, that a refund scheme may be considered contrary to good advertising practice.

Furthermore, it is prohibited in consumer advertising to suggest that the effects of the product are guaranteed, or that its use is not associated with any adverse effects, or suggest without grounds to prove that the effects are equally good or better than those of another treatment or medication.

The nature of the product, whether it is a prescription-only or an over-the-counter product, does not make any difference.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Pharmaceutical companies may sponsor further or complementary training. However, according to the Finnish Medicinal Association, events organised by pharmaceutical companies themselves do not fulfil the requirements for post-graduate or further professional education (i.e. no CME accreditation). When a pharmaceutical company sponsors a scientific event, the attendees and invitees must be clearly informed of this. Furthermore, pharmaceutical companies may participate in the expenses of further complementary training only if the company is provided with a possibility to actively distribute information of their products in the training event.

According to the Guidelines concerning Continuing Medical Education (2007) published by the Finnish Medicinal Association, it is further recommended that physicians and other healthcare professionals participating, e.g. as lecturers in continuing medical education events sponsored by pharmaceutical companies, disclose their financial and other interests (e.g. grants and awards received from the pharmaceutical industry, shareholding in pharma companies, etc.). The conflict of interest disclosure should be made in the programme of the event.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The Finnish Criminal Code (39/1889) contains the general anti-bribery rules regarding the giving and accepting of a bribe. The Criminal Code contains provisions on active bribery of a public official or a Member of Parliament, passive bribery of a public official or a Member of Parliament, active bribery in business and passive bribery in business. The Criminal Code also contains provisions on aggravated forms of the mentioned crimes. The provisions of the Criminal Code apply to the interaction between pharmaceutical companies and healthcare professionals or organisations if the interaction meets the essential elements of the offence set forth in the Criminal Code.

Finland does not have a special authority focusing particularly on investigating bribery-related offences. As it is the case with other offences, the police force is responsible for investigating such offences. In cases of a more complex nature, i.e. involving organised crime, international connections or involvement of senior public officials, the investigations are normally conducted by the National Bureau of Investigation. After the investigation has been completed, the case is turned to the prosecutorial service for consideration of charges. Fimea monitors that the medicinal products are advertised according to the Medicines Act and Decree. Also, the PIF monitors the appropriateness of the advertising of medicinal products by PIF's member companies and compliance with the PIF Code.

The police force shall conduct an investigation when, on the basis of a report made to it or otherwise, there is a reason to suspect that a crime has been committed. Thus, the police force may start an investigation even though the matter is already subject to assessment by Fimea or PIF. See question 1.8 on the relationship regarding the processes instituted by PIF and competent authorities.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

According to the PIF Code, events organised or sponsored by the pharmaceutical industry shall observe the customary local norms of hospitality. The hospitality must be reasonable and suitable to the situation, as well as secondary to the purpose of the event. Furthermore, hospitality must not exceed what typical participants in the event would be prepared to pay if they had to cover their own expenses. Hospitality shall reinforce the positive public image of the pharmaceutical industry and may not endanger the public trust towards neutrality of medicine subscription and supply. The overall daily expenditure on meals (food and beverages) per participant must not exceed EUR 45 for lunch and EUR 100 for dinner.

Scientific or training events may take place abroad provided they have sufficient scientific- or training-related justification. The PIF Code of Ethics must also be followed in pharmaceutical advertising and other operations falling within the scope of application of the Code, targeted at Finns abroad or in international congresses. In addition, local instructions and requirements should be adhered to. Please also see question 5.2 below.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

According to the PIF Code, the pharmaceutical industry may participate in the costs of updating or advanced healthcare training, provided the industry is given the possibility to participate in the information activity. The main focus of the event shall be medical information, or it will relate to medical research. The majority of the participant's time shall be consumed in scientific programmes or training. The costs shall essentially relate to scientific programmes and information, and be allocated only to professionals who receive the information.

The event shall take place at a location which is suitable, taking into account the scientific or training programme of the event. The event may not be organised in a "luxury" location or at a resort known for its spare time and entertainment activities. The event may also take place abroad provided it has sufficient scientific or training-related justification.

The cost may only include registration, travel, accommodation and meal expenses of the scientific or training event. Payment for the attendee's time is not allowed.

The event and travel time must be organised so that, excluding travel days, the majority of the participant's time will be spent on scientific programmes and training.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

The hospitality arrangements for scientific meetings are most likely considered advertising within the meaning of the Medicines Act and Decree, and the issues highlighted in questions 5.1 and 5.2 above must be followed in such hospitality arrangements.

Fimea may prohibit a company from continuing or repeating hospitality arrangements that violate the provisions of the Medicines Act and Decree. A conditional fine may support a prohibition or order issued by Fimea (see question 1.6).

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Basically, yes. However, the payment should be reasonable and it should strictly relate to professional activities. Otherwise, there is a risk that such payment will be considered as an inappropriate gift. In their cooperation with doctors, companies must ensure that the agreement relating to the compensation is not used to circumvent the rules and regulations on the promotion of medicinal products.

The use of healthcare professionals as a group or as individual consultants or advisers must be arranged to meet certain criteria defined in the PIF Code (e.g. a written contract is required, consultants are liable to disclose their relationship to the company whenever writing or speaking publicly about the subject matter of the consultation relationship).

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

It is not prohibited for physicians to take part in post-marketing surveillance (see also question 5.3). According to the PIF Code, in organising market research, special attention must be paid to the protection of the privacy of the patients, as well as to the voluntary participation in such research. In addition, market research must not have an impact on the treatment of individual patients and should be based on objectiveness, and the compensation paid for the implementation of the research must be of reasonable economic value. Market research must also be limited in scope and the opinion of healthcare professionals must not be asked repeatedly. Market research may not contain any elements of advertising and the research may only be conducted on medicinal products with valid marketing authorisations.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

See questions 2.7, 5.4 and 5.5 above. With regard to market research, it is permissible to compensate healthcare professionals for their participation, but according to the PIF Code the amount of the remuneration shall be minor. PIF has considered EUR 35 to be an acceptable compensation, but if it is a case of extensive research which takes more time, the acceptable level of remuneration may amount to EUR 100.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Advertising of medicines shall encourage the appropriate use of the medicines, and information given in advertising must correspond to the summary of product characteristics. Advertising may not solicit the general public to an unnecessary use of medicines, provide a misleading or exaggerated picture of the formula, origin or significance as a medicine, or otherwise be inappropriate. Products may be advertised as medicines only if defined as such pursuant to the Medicines Act.

Advertisements to the general public shall include the product name and the name of the active ingredient, if the product contains only one active ingredient, as well as information necessary for the correct and safe use and an explicit and easily readable request to read separate instructions. According to the PIF Code, the advertisement must also include the indication and the name of the holder of the marketing authorisation, importer or marketer.

It is prohibited to include in advertisements to the general public groundless statements regarding health or direct advertising at children or give an exaggerated or misleading picture of the effects of a medicinal product.

Advertisements to the general public must not refer to clinical trials in such a way that a false picture is given of the conclusion, extent or significance of the trials. According to the Medicines Decree, advertisements to the general public shall be set out in such a way that it is evident that the message is an advertisement of medicinal products and must not include any information that:

- gives the impression that it is unnecessary to consult a doctor or that a treatment recommended by a doctor is not necessary;
- suggests that the effects of the product are guaranteed, or that its use is not associated with any adverse reactions, or suggests that the effects are equally good or better than those of another treatment or medication;
- suggests that the health of the subject can be enhanced by taking the medicine or that the health of the subject could be affected by not taking the medicine;
- is directed solely or mainly at children;
- refers to a recommendation by scientists, healthcare professionals or celebrities;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the therapeutic effect or safety of the medicinal product is based on its origins from nature;
- could easily lead to an incorrect self-diagnosis or self-cure due to a detailed representation of a case history;
- refers in inappropriate, intimidating or misleading terms to claims of recovery;
- uses inappropriate, intimidating or misleading terms, pictorial representations of changes caused in the human body by disease or injury, or of the effect of a medicinal product in the human body or its parts; or
- mentions that the medicinal product has been granted a marketing authorisation.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

It is prohibited to market prescription-only medicines or medicines containing narcotics or psychotropic substances to the general public.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are allowed, provided they are not, even indirectly, intended to promote the sale of a medicine. Notwithstanding question 6.2 above, it is acceptable to provide information on prescription medicines to the general public, provided the information only contains essential information consistent with the summary of product characteristics or the package insert. The information given can also refer to prescription-only medicines if the information is of an impartial and factual nature, and covers all alternative medicines on the market. In such cases, sufficient information on non-medicinal forms of treatment must also be given. The PIF Code contains more detailed criteria for awareness campaigns, concerning, e.g., the visual image of the awareness information and internet sites containing health awareness material.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Please see questions 2.3 and 6.3 above and question 6.5 below. In case developments as to unauthorised medicines or unauthorised indications are referred to, the publication should not involve any elements of advertising whatsoever.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Information focusing primarily on the operations of the company, as well as corporate image advertising and business representation with no direct objective of promoting sales of medicines, are excluded from the scope of the PIF Code. In addition, press releases based on the information that a pharmaceutical company is obliged to provide, as well as informative notices (e.g. changes in packaging or warnings about adverse effects), are not considered promotional according to the Medicines Decree.

It should be noted, however, that the advertising provisions of the Medicines Act and Decree and the PIF Code apply to all forms of advertising and promotional activities by pharmaceutical companies, and the context and subject matter are decisive in determining whether or not an activity amounts to the promotion of medicinal products. A non-promotional item may be used for a promotional purpose and therefore come within the scope of the relevant legislation and industry rules. Consequently, material issued by companies which relates to medicines, but which is not designed as a promotion for those medicines, such as corporate information, press releases, financial information for shareholders and the Stock Exchange and responses to unsolicited enquiries from the public, should be examined to ensure that they do not contravene the Medicines Act or Decree or the PIF Code.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

The PIF Code contains guidelines on cooperation with patient organisations. In the PIF Code, it is also stated that the EFPIA Code should be applied. Providing support to patient groups is not prohibited as such. However, the (financial) support shall not be used to circumvent the legislation and PIF Code. Donations are only allowed if their purpose is to support healthcare and research, and if information regarding donations is properly documented and filed by the donator. Donations will not be accepted in cases where the nature of the cooperation may jeopardise the public trust in the impartiality of the prescription and supply of medicines. All donations and sponsorship, direct or indirect, should be disclosed by pharmaceutical companies to ensure transparency. It should also be noted that in the materials and publications created jointly by a patient organisation and the pharmaceutical company, the editorial material shall be based on editorial initiatives and assessments. The editorial and promotional material shall be clearly separated. Finally, when a pharmaceutical company sponsors, e.g., a scientific event organised by the patient organisation, this should be clearly indicated in the invitations and programmes.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

As a general rule, restrictions on advertising to consumers apply to patients as well. Giveaways or medicinal product samples cannot be distributed to consumers in sales promotion. In addition, prize-winning competitions and lotteries are prohibited. Please also see questions 6.1 and 6.2 above.

Patient instructions must always be delivered by the company to physicians or other healthcare professionals, and they must not be generally available to consumers. When delivering the material, the recipient must be informed clearly that the patient instructions are merely intended for particular patients to support the treatment prescribed to them, and are not generally distributable to all patients.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

There is no express obligation to disclose details of clinical trials in advertising.

However, the Medicines Decree stipulates that advertising materials may not omit an essential detail, the omission of which could give a false impression. Further, according to the Medicines Decree, advertising may not refer to any clinical trial in a way that misrepresents the conclusions, extent or significance of the trial.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Yes. The Medicines Act stipulates that the holder of a marketing authorisation or other entity advertising a medicine should make publicly available, e.g. on the company's webpage, an updated list of direct or indirect economic or other benefits which it has granted to medical or healthcare associations or patient organisations. The disclosure obligation concerns both national and foreign companies that are advertising their (authorised) products in Finland.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Yes. There is a requirement in the PIF Code for companies to make publicly available transfers of value annually provided by them to healthcare organisations and healthcare professionals who have their place of business in Europe. The disclosure obligation concerns both national and foreign member companies of PIF that are advertising their (authorised) products in Finland.

The member companies of PIF will be affected by the rules regarding the disclosure of transfers of value. The first reporting period for which these rules apply is the calendar year 2015. As a main rule, the economic liaisons are published by specifying the name of the recipient, while the values of the economic benefits received by the individual recipient are published for each reporting period by classifying them in certain stipulated categories, e.g. donations and grants, contributions to the costs of events and service and consultations fees. The economic benefits received by a recipient can be published by annual aggregate categories, provided that the individual sums can be presented on request.

The publication should be done in the Finnish language on the company's webpage, following PIF's template. The company must provide a brief presentation of the methods used in the publication and identification of each category. The publication takes place annually within six months from the end of each reporting period. The reporting period is one full calendar year. The data must be kept publicly accessible for at least three years, and stored for at least five years.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Due to data protection regulations, the publication of data on individuals requires consent from the person in question. If such consent is not obtained, the data is disclosed without the name of the person involved. However, the associations of Finnish healthcare professionals generally support the disclosure.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

No, there are no legal or code requirements for companies to have specific standard operating procedures, although most companies have such in place.

Basically, the same rules apply to internet advertising as to advertising through other media. Advertising products which are to be sold by prescription, or which contain narcotics or psychotropic substances, is prohibited unless aimed at persons entitled to prescribe those medicines.

Based on our experience, the Finnish authorities react quite expediently to internet advertising, as they do not consider them to be fulfilling the legal requirements. The companies usually agree to change their advertising after having received a notice thereof.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

According to the Medicines Act, electronic advertising to healthcare professionals shall be implemented in such a secure manner that it cannot target the general public. Thus, if advertising is carried out through electronic media, such as an extranet or another limited access system, the advertiser must ensure that unauthorised persons cannot access it (e.g. passwords and registration requirements for physicians). A general warning such as "information for medical professionals only" is not sufficient.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

The content restrictions set by the Finnish regulations regarding the advertising of medicinal products also apply to websites accessed by links. According to the guidelines on the advertising of medicinal products produced by Fimea, independent websites that may be accessed by links from a company website need to comply with the Finnish regulations even if the independent website is in a language other than Finnish or Swedish. Consequently, it is prohibited to have a link to a website in which advertising prescription-only medicinal products or products containing narcotics or psychotropic substances are advertised unless the site is only accessible to persons entitled to prescribe those medicinal products (see also question 7.2). There are no specific rules based on which the company would be held responsible for reverse linking.

The holder of the marketing authorisation is responsible for compliance with the Finnish legislation of an independent website which is accessible by link from the marketing authorisation holder's website.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Advertising of prescription-only medicinal products or products containing narcotics or psychotropic substances to the general public is prohibited under the Medicines Act. However, a pharmaceutical company may publish the summary of the product characteristics or the package leaflet approved by an authority on the company's website, provided that the summary or the insert has not been amended or abridged.

It is deemed possible to publish user instructions of such medicinal products whose dosing requires particular knowledge or use of particular auxiliary means; e.g. user instructions for inhalers or insulin pens.

A pharmaceutical company may generally also briefly mention that a particular medicinal product or active ingredient is used for the treatment of a particular disease. Demonstration of, *inter alia*, indications, therapeutic statements, effects or other such features of the medicinal product may, however, be considered advertising, which is prohibited as regards prescription-only medicinal products.

The acceptability of published information is considered on a case-by-case basis depending on the context of the information.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

No specific regulation exists. The same rules basically apply to social media as to advertising through other media.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

Mobile applications are continuing to be used as a means of advertising, meaning that the obligation of companies to ensure compliance with the relevant regulation also when cooperating with third parties is accentuated. It is also noteworthy that the supervision of compliance with legislation concerning medical and IVD medical devices will be transferred from the National Supervisory Authority for Welfare and Health ("Valvira") to Fimea by the end of 2019. This means that Fimea's competencies are broadened to also cover the advertising of medical and IVD medical devices.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

There are no expected significant developments in the next year.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

There are no major changes in general practice or enforcement that have become apparent in 2018.

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# France

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products in France is mainly regulated by:

- Articles L. 5122-1 to L. 5122-16 and R. 5122-1 to R. 5122-17 of the French Public Health Code (the "**FPHC**") relating to advertising of medicinal products for human use;
- Articles L. 121-2 to L. 121-7 and L. 122-1 to L. 122-10 of the French Consumer Code, relating to prohibited and regulated commercial practices;
- Articles L. 1453-1 to L. 1454-10 of the FPHC, relating to transparency and anti-gifts principles;
- Article L. 162-17-4 of the French Social Security Code; and
- Law n° 94-665 as of August 4, 1994, requiring that all advertising be drafted in French.

The following various recommendations or codes also apply:

- the recommendations issued by the French National Agency for the Safety of Medicinal and Health Products (the "*Agence nationale de sécurité du medicament et des produits de santé*", the "**ANSM**");
- the "Charter for the information by doorstep selling or prospection aimed at promoting medicinal products" ("*Charte de l'information par démarchage ou prospection visant à la promotion des médicaments*"), signed by the Economic Committee of Medicinal Products ("*Comité économique des produits de santé*", the "**CEPS**", being the French competent authority for price fixing) and the French association of pharmaceutical companies ("*Les entreprises du medicament*", the "**LEEM**") dated October 15, 2014;
- the "Charter for the communication and the promotion of health products on the Internet and e-media" ("*Charte pour la communication et la promotion des produits de santé (medicaments et dispositifs médicaux) sur Internet et le e-media*") issued by the ANSM;
- the "Ethical professional provisions" ("*Disposition déontologiques professionnelles*") issued by the LEEM, which contain notably the provisions of the codes of good practices issued by the European Federation of Pharmaceutical Industries and Associations ("**EFPIA**") and the Federation of Pharmaceutical Manufacturers & Associations ("**FIIM**"); and
- the code named "Information on the medicinal product and editorial advertising" ("*Information sur le médicament et publicité rédactionnelle*") issued by the LEEM and by the SPEPS and UDA (media associations).

### 1.2 How is "advertising" defined?

Advertising is defined by Article L. 5122-1 of the FPHC, as any kind of information, including doorstep selling, prospection or inducement aimed at promoting the prescription, supply, sale or use of medicinal products, to the exception of information delivered by pharmacists managing hospital pharmacies.

According to Article L. 5122-1 of the FPHC, the following shall not be considered as "advertising":

- correspondence, together with, as the case may be, non-advertising documentation, necessary to answer a precise question relating to a specific medicinal product;
- concrete information and reference documents related, for example, to packaging modification, warnings concerning adverse effects identified in the context of pharmacovigilance, and sales catalogues and price lists, provided they do not contain any information on the medicinal product; and
- information relating to human health or human diseases, provided there is no reference, even indirectly, to a medicinal product.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Pursuant to Article R. 5122-1 of the FPHC, pharmaceutical companies must have a department in charge of advertising, under the supervision of the responsible pharmacist of the company, who must ensure companies' compliance with the provisions of the FPHC and, in particular, the scientific accuracy of the information released.

Furthermore, companies must keep a copy of each published advertising during three years from the last diffusion of such advertising and must make it available to the ANSM, which can have access to them upon request.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

In addition to the above (see question 1.3), Article L. 5122-11 of the FPHC provides that the personnel in charge of the promotional activities by doorstep selling or prospection (e.g., sales representatives)

must have a scientific knowledge certified by a diploma, credentials or a certificate listed by a competent administrative authority.

Employers have the responsibility of checking that this knowledge is genuine and up to date.

In addition, the Charter for the information by doorstep selling or prospection aimed at promoting medicinal products also contains requirements for companies to provide to their employees (in particular, sales representatives) continuous educational training.

Furthermore, in the context of the price fixing process, pharmaceutical companies commercialising medicinal products reimbursed by French social security schemes have to sign a specific contract with the CEPS. In this respect, they have to comply with the requirements of the Charter for the information by doorstep selling or prospection aimed at promoting medicinal products. Moreover, pursuant to Article L. 162-17-4 of the French Social Security Code, compliance of such companies with those requirements is subject to an evaluation and certification process by accredited organisms, based on certification rules established by another authority, the French Public Health Authority (French "*Haute Autorité de Santé*", the "**HAS**").

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

Pursuant to Articles L. 5122-8 and L. 5122-9 of the FPHC, the advertising to both the general public and healthcare professionals ("**HCPs**") shall be approved in advance by the ANSM, which is in charge of delivering the corresponding "visa" (i.e., name of the relevant authorisation). The request for authorisation must be submitted in accordance with a specific agenda determined by the ANSM and detailed on the ANSM website. The model forms and the list of required documents (in paper and electronic format) are also available on the ANSM website.

For the advertising to the general public and to HCPs, the visa is considered as delivered in the absence of any decision by the ANSM within a two-month delay further to the receipt, by the ANSM, of the application.

Visas are valid for a two-year period.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

If an advertisement for the general public or for HCPs is in breach of the law, the visa can be removed upon the reasoned decision of the ANSM, after the company has been invited to submit its comments in a delay that cannot be less than one month. In case of emergency, the ANSM can suspend the visa, with immediate effect, for a maximum period of three months (Articles L. 5122-8 and 9 and Articles R. 5122-7 and R. 5122-15 of the FPHC).

Decisions of the ANSM are in principle published on the ANSM's website.

The ANSM also has a general power to pronounce injunctions. It is not entitled to specifically request the issue of a corrective statement, however, if an unlawful advertising entails a risk for the general public, the ANSM may presumably request the issue of such a corrective statement.

The decisions of the ANSM can be appealed before the French administrative Courts.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The ANSM can pronounce financial sanctions for failing to comply with the rules governing the advertising of medicines, with optional daily penalties (Articles L. 5312-4-1 and L. 5471-1 of the FPHC). As the case may be, the ANSM can order the concerned company to regularise its situation, and enable it to present its observations, with a possibility of being assisted by an advisor.

Pursuant to Article L. 5422-18 of the FPHC, the following unlawful promotional activities for medicinal products are subject to financial sanctions:

- advertisements for medicinal products which have not obtained the relevant product marketing authorisation for commercialisation;
- advertisements whether made for the general public or for HCPs, which have not obtained the "visa" (i.e., the authorisation – see question 1.5) delivered by the ANSM, or which are realised despite the suspension or withdrawal of such "visa";
- advertisements made for the general public for a prescription only medicinal product;
- advertisements made for the general public for a medicinal product reimbursed by the French social security schemes, except for certain vaccines;
- advertisements made for the general public for a medicinal product subject to limitations regarding advertisements for the general public, due to the potential risk on public health; and
- advertisements made for the general public or for HCPs for a medicinal product subject to an authorisation for temporary use ("*Autorisation temporaire d'utilisation*", ATU).

The financial sanction cannot exceed €150,000 for individuals and, for companies, 30% of the turnover made on the concerned product(s) during the last financial year, within the limit of €1 million (Article L. 5471-1 of the FPHC).

The ANSM can also pronounce, in addition to the above financial sanctions, daily fines.

Decisions relating to the above financial sanctions can be published on the ANSM's website.

To our knowledge, there is no recent important example where a financial sanction has been pronounced by the ANSM in relation to an advertisement for medicinal products. The number of such financial sanctions is rather low (for example, there were no more than five cases for 2017). Most of the time, the ANSM pronounces injunctions, suspensions or withdrawals of the "visa", and more rarely, financial sanctions.

Besides, the FPHC also contains criminal sanctions regarding advertising, which can be pronounced by French Courts.

Pursuant to Article L. 5421-2 of the FPHC, the promotion of medicinal products which have not obtained the relevant marketing authorisation, or whose authorisation has been refused, suspended, withdrawn, or is outdated, is punished by five years of imprisonment and a fine of €375,000 (€1,875,000 for legal entities). Some

aggravating circumstances may even lead to seven years of imprisonment and a fine of €750,000 (€3,750,000 for legal entities).

Also, pursuant to Article L. 5422-8 of the FPHC, every advertisement which was not authorised by a "visa" or whose "visa" was suspended or withdrawn, is punished by one year of imprisonment and a fine of €150,000 (€450,000 for legal entities).

Regarding advertising to the general public, infringers are notably subject to one year of imprisonment and a fine of €150,000 (€450,000 for legal entities) every advertisement for:

- a medicinal product subject to an authorisation for temporary use (Article L. 5422-3 of the FPHC);
- a prescription only medicinal product (Article L. 5422-5 of the FPHC);
- a medicine which is reimbursed by the French social security schemes (Article L. 5422-5 of the FPHC); or
- a medicine with which the marketing authorisation contains restrictions relating to the potential risk to the public health (Article L. 5422-5 of the FPHC).

In addition to the above criminal sanctions, pharmaceutical companies declared criminally liable may also be subject to additional sanctions listed in the French Criminal Code, such as, among others, the exclusion from the public procurement tenders.

Also, pursuant to Article L. 162-17-4 of the French Social Security Code, if a "visa" relating to an advertisement for HCPs has been withdrawn by the ANSM, the CEPS can pronounce a financial fine against the concerned company, amounting to up to 10% of its turnover realised in France (excluding VAT) with the concerned medicinal product during the six months before and six months after the date of withdrawal of the "visa".

Competitors may also take direct action through the civil courts in relation to advertising infringements, on the grounds of unfair competition, and seek indemnification.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

In France, the self-regulatory body is the CODEEM ("*Comité de Déontovigilance des Entreprises du Médicament*"), which is the committee, created by the LEEM in 2011, responsible for ensuring that members of the LEEM comply with the self-regulatory ethical rules established by the LEEM. Among its prerogatives, the CODEEM has a mediation and sanctioning role: it organises mediations in the event of a dispute relating to ethical questions; and it has the power to pronounce sanctions (which can range from a formal warning to an exclusion from the LEEM) in case of non-compliance by a member with ethical rules.

As a general principle, there is no specific relationship between the self-regulatory process of the pharmaceutical industry and the supervisory and enforcement function of the competent authorities. As a consequence, the decisions or other measures of a self-regulatory body such as the CODEEM do not have any legal impact on the potential actions of the French competent authorities.

In practice, French competent authorities may investigate matters drawn to their attention that may constitute a breach of both the laws and any relevant self-regulatory code, even though such matters are already being assessed by the competent self-regulatory body. In every case where there is an infringement of applicable laws and regulations, French competent authorities are entitled to investigate the case. They are not supposed to, however, investigate matters that would only constitute a breach of a self-regulatory code of practice or ethical code.

Although there is not a specific provision in this respect, French competent authorities may also take up a matter based on an adverse finding of any self-regulatory body, if such matter relates to a breach of applicable laws or regulations. Conversely, the self-regulatory body may presumably take up a matter based on adverse findings of French competent authorities. In this respect, whenever a matter is brought before the CODEEM while being brought before a Court, the CODEEM can stay proceedings and await the decision of the Court.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

In the event that the infringement of the laws and regulations relating to pharmaceutical advertising also constitute an act of unfair competition, it is possible to take action directly before the French commercial Courts. As a general principle, non-compliance of a competitor with applicable laws and regulations can constitute an act of unfair competition.

Any person may bring such action. In practice, this person will have to demonstrate a fault (e.g., breach of applicable laws and regulations), a damage (e.g., loss of profits due to the unlawful promotional activities of a competitor) and a causal link. In such case, the competitor can be sentenced to pay damages, calculated based on the estimated loss of profits of the claimant due to the unfair practices, or based on the estimated gains of the competitor due to such unfair practices. Public releases can also be pronounced.

The claimant may also request from the Court a ban on the advertising under emergency proceedings.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

In the context of promotional activities, HCPs can only be provided with information relating to authorised medicinal products. Therefore, information about a medicinal product before that product is authorised can be made available to HCPs only if such information is not promotional.

The exchange of information relating to an unauthorised medicinal product during the development phase is also possible, provided that such exchange of information is not considered as promotional. For example, such exchange of information can be made during independent scientific committees, meetings or congresses (i.e., committees, meetings or congresses which programmes/presentations are approved by an independent committee and are purely scientific, with

no branding and only reference to the International Non-proprietary Name ("**INN**"), even sponsored by a pharmaceutical company).

The position is the same with regard to the provision of off-label information. In this respect, companies can also provide to a HCP scientific information (on-label and off-label), to respond to a specific unsolicited question from said HCP about a particular product. Indeed, such communication of information is deemed to be non-promotional. However, the information provided to the HCP must not go beyond the scope of the question (otherwise, such communication could be considered as promotional).

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

In relation to independent congresses or meetings, medical press publishers can issue special editions to report all or part of the work presented during such congresses or meetings. Whenever these special editions contain research data that have not been validated by French authorities, this shall be clearly specified by a warning on the first page of the edition.

The publication of these special editions, as well as their content, is made under the sole responsibility of the publishers and their reading committees. These publications can contain advertisements, excluding for medicinal products mentioned in the edition and for which off-label information is provided.

The distribution of these special editions is made under the sole responsibility of the publishers and shall not be repeated. If these special editions contain off-label information, their use in the context of promotional activities (notably, their use by sales representatives) is prohibited.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Press releases issued by pharmaceutical companies can be considered as promotional. Therefore, press releases must be made with extreme caution. A press release about unauthorised medicinal products and/or off-label information is permitted if such press release is not intended to promote the medicinal product itself, but to present a development achievement of the company from a scientific perspective. In this respect, the press release must be factual and not include allegations or any cheerful description.

In practice, press releases are supposed to be sent to journalists or chief editors, and not be accessible to the general public or to HCPs.

The code named "Information on the medicinal product and editorial advertising" ("*Information sur le médicament et publicité rédactionnelle*") issued by the LEEM and by the SPEPS and UDA (media associations) states that pharmaceutical companies have to reserve press conferences to important matters, that are, among others, original research started by a pharmaceutical company, clinical study results, economic and financial results or industrial restructuration, etc. It is the companies' responsibility to be selective regarding the matters to be developed, and the editors' responsibility to assist with press conferences, depending on the appropriateness of the information for their target audience. Attention has to be paid by the two parties to ensure that the press conference and related reports are not qualified as promotional. Invitations have to be addressed to media redaction.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

No, such information (press releases) cannot be sent to HCPs, except in response to a specific unsolicited request from a HCP. In such case, the information provided to the HCP must not go beyond the scope of the his/her question (i.e., the information contained in the press release must correspond exactly to the information request – if this is not the case, the press release should not be sent (see also question 2.1 concerning unsolicited questions from HCPs)).

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Article L. 5122-1 of the FPHC provides that information contained in sales catalogues and price lists are not considered as promotion, provided they do not contain any information on the medicinal product. This principle was already included in the FPHC before the decision in the *Ludwigs* case.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

The FPHC does not provide for any specific exception in this respect. In practice, such information is likely to be considered as promotional if it is communicated (even indirectly) to HCPs, except where such information is communicated in response to a specific request from a HCP.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Yes, provided the contractual relationship complies with standards required for services agreements (notably, such contractual relationships must comply with principles applicable to services agreements with HCPs – see question 5.4) and that the real purpose of the market research is to obtain feedback from HCPs, and not to communicate information on unauthorised products or information to said HCPs. There are no official guidelines on that topic.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The following mandatory information, listed by Article R. 5122-8 of the FPHC, must appear in advertisements directed to HCPs:

- the name of the medicinal product;
- the name and the address of the pharmaceutical company;
- the pharmaceutical form;
- the composition;
- the number of the related marketing authorisation;
- the pharmaceutical properties with respect to its indications;
- the therapeutic indications and contraindications;
- the method of administration;
- the posology;
- the side effects;
- the specific precautions for use;
- the drug interactions;
- the classification of the medicinal products in terms of prescription and delivery;
- the maximum sale price;
- the position regarding reimbursement; and
- any additional information if the medicinal product is a generic one.

Such mandatory information is the same regardless of the support (electronic, paper, audio-visual media).

### 3.2 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

As a general principle, an advertisement mainly based on the results of an opinion survey is prohibited. However, it may be allowed if such results are in line with the marketing authorisation, the option of the Transparency Commission (which is the competent commission for evaluation of the medical benefit of medicinal products), and the proper use of the medicinal product.

In any case, an individual endorsement by a HCP in promotional materials is not allowed. Notably, pursuant to Article R. 4127-20 of the FPHC, the HCP shall ensure the accurate use of his/her name, profession and statements. He/she must not accept that private or public entities he/she works for or he/she assists use his/her name or his/her professional skills for promotional activities.

### 3.3 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Pursuant to Article L. 5122-2, the advertisement must not be misleading.

As a general principle, the elements contained in the advertisement must conform to the SmPC.

Also, information contained in an advertisement shall be accurate, updated, verifiable and exhaustive in order to allow the HCP to make his/her own opinion on the therapeutic value of the medicinal product. Quotations, citations, tables and other illustrations from medical journals or scientific medias used for promotion shall be quoted faithfully and shall specify the source (Article R. 5122-9 of the FPHC).

As concerns studies, according to the recommendations issued by the ANSM, studies that can be used for promotion are the ones published in peer-reviewed journals, conducted in accordance with the conditions of use of the medicinal product, as defined in its marketing authorisation.

Please note that the following non-published studies can be used in the context of promotional activities:

- studies referred to in the marketing authorisation dossier and which comply with the terms of the marketing authorisation; and
- as the case may be, studies selected and used by the Transparency Commission to issue its opinion, and which comply with the conclusions of the Transparency Commission.

These studies shall be communicated to any HCP requesting so.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No, there is no explicit written requirement under French law.

However, comparison shall be as exhaustive as possible and, in order to be objective, shall be made on essential, significant, relevant and ascertainable characteristics, which implies that the comparison be based on relevant data.

For further detail concerning comparative advertisements, see question 3.5.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

General comparative advertisements are regulated under the French Consumer Code (Articles L. 122-1 and L. 122-2), and they are considered to be lawful provided that:

- they are not misleading or likely to be misleading;
- they relate to products that respond to the same needs or have the same purposes;
- they objectively compare at least one or more essential, relevant, ascertainable and significant characteristics of the products (including the price as the case may be);
- they do not take undue advantage of the reputation attached to a manufacturer brand, commercial trademark or service brand, to other distinctive trademarks of a competitor or to the protected designation of origin or geographical indication of a competing product;
- they do not lead to the discredit or the denigration of the trademark, trade name, other distinctive signs, goods, services, activity or situation of a competitor;
- they do not lead to the confusion between the advertiser and a competitor or between the trademarks, commercial names, other distinctive marks, goods or services of the advertiser and the competitor; and
- they do not present goods or services as an imitation or a reproduction of a good or service having a protected mark or commercial name.

Besides the above general principles, the ANSM issued recommendations regarding pharmaceutical products as follows:

1) **Products subject to comparison**: comparative advertising may concern two or more products, under their brand name or under their INN. They may be products from the same therapeutic class, or from different chemical classes, but in any case, with the same therapeutic use.
2) **Comparison criteria**: comparison shall be as exhaustive as possible, without giving priority exclusively to positive elements. To this end, comparison shall concern essential characteristics, and significant, appropriate and verifiable information. Comparison shall at least contain efficiency and security criteria (risk/benefit ratio). Comparison may also indicate useful details for the HCP such as posology, treatment period, interaction, acceptance, etc. Comparison shall not detail pharmacological properties without any validated clinical result.

3) **Comparison of costs**: the ANSM recommends comparing the costs of the treatment (instead of the strict prices of the products), which are more relevant, provided the prices are published.

4) **Types of studies that can be used for comparative advertisements**: the studies (whether published or not) referred to in the marketing authorisation dossier and studies selected and used by the Transparency Commission to issue its opinion, provided they comply with the therapeutic indications validated by the marketing authorisation and, if any, with the opinion of the Transparency Commission opinions. However, other clinical studies (i.e., studies that are not specifically referred to in the marketing authorisation dossier nor in the opinion of the Transparency Commission) may also be used for promotion provided they are in line with the indications validated by the marketing authorisation and the opinion of the Transparency Commission; in such case, they must have been published in a peer-reviewed journal.

5) **Presentation of the results of the comparison**: the information so provided shall be clear, accurate, balanced and processed in a homogeneous way.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

If such scientific papers and/or proceedings of congresses contain only on-label information, they can be distributed to HCPs in the context of promotional activities. In such case, companies must obtain a "visa" from the ANSM and insert mandatory legal mentions on the promotional material.

As concerns scientific papers and/or proceeding of congresses which contain off-label information, see response to question 2.2.

### 3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

There is no specific regulation relating to "teaser" advertisements under French law. Therefore, such advertisements should be permissible provided they comply with laws and regulations relating to the promotion of medicinal products. Indeed, the "teaser" and its content shall be reviewed carefully in order to determine whether it has to be considered as a medicinal product advertising – depending on the information contained in such "teaser": in such case, it must relate to a product which has been duly authorised, and contain all the mandatory information (see question 3.1) which may be contradictory in the nature of what is usually considered as a "teaser".

### 3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

In our opinion, the holder of product A should be able to rely upon the approved use of product B with product A to promote the combination use, provided it respects the marketing authorisation of product A and the recommendation issued by the French HAS, and provided it participates in the good use of the medicinal products.

However, the holder of the MA for product B shall first vary the SmPC before requesting the "visa" in order to be compliant with the MA.

## 4 Gifts and Financial Incentives

### 4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

The provision of free samples of medicinal products to HCPs is subject to specific conditions, set forth by Articles L. 5122-10 and R. 5122-17 of the FPHC.

Free samples can be provided only to persons qualified to prescribe or supply them.

The provision of free samples is allowed only for two years following the first effective commercialisation, in France, of either (i) a medicinal product authorised for the first time, or (ii) a product already authorised, for a new dosage or a new pharmaceutical form, provided the authorisation is extended.

The provision of free samples of medicinal products must also comply with the following conditions.

Such samples may be provided only upon a written, dated and signed request from the recipient.

The number of free samples that can be provided is limited to four samples per year and per recipient. Each sample shall not be larger than the smallest presentation on the market and contain the following mention: "free sample". Each sample shall be accompanied by a copy of the summary of the product characteristics.

When the product is subject to restricted prescription, the samples can be distributed only to the HCPs qualified to prescribe it and to the head pharmacist of hospital pharmacies within hospitals.

No samples of medicinal products containing psychotropic or narcotic substances may be supplied.

Also, it should be mentioned that the direct supply of free samples to the general public for promotional purposes, as well as the supply of free samples in medicinal or pharmaceutical congresses which are accessible to the public, are prohibited.

### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Pursuant to Article L. 1453-3 of the FPHC, it is prohibited for (i) HCPs, (ii) students intending to practice a healthcare profession, (iii) associations grouping HCPs, and (iv) public agents who participate to the drawing up of the public-health policy or who have administrative police powers, to receive "advantages" (gifts or donations), whether in cash or in kind, directly or indirectly, from any person or entity commercialising health products (which of course includes pharmaceutical companies). It is also prohibited for such persons or entities to provide to HCPs (and to other people/entities mentioned above) any such advantages (Article L. 1453-5 of the FPHC).

These anti-gifts provisions, which have been modified recently by a Law dated January 26, 2016 and by an Ordonnance dated January 19, 2017 and which are now set out in Articles L. 1453-3 *et seq*. of the FPHC, have entered into effect on July 1, 2018, except for the

provisions which need the publication of an implementation decree. The prohibition is now applicable to any person or entity commercialising health products (e.g., pharmaceutical companies), and not only to those companies which products are reimbursed by the social security schemes (as was the case under the former set of rules).

As concerns advantages in cash or in kind of a "negligible value", the FPHC expressly provides that, if they are related to the HCPs' practice and do not exceed an amount determined by an *Arrêté* (specific decision to be taken by the competent Ministry), they are not considered as prohibited advantages (Article L. 1453-6, 4° of the FPHC). The above-mentioned *Arrêté* has not yet been published. However, until then, the commonly accepted maximum amount taken into account is €30, which is the limit recommended by the French Medical Board.

For the sake of completeness, the FPHC (Article L. 1453-7) also provides for derogations to the general prohibition, namely:

- the remuneration and compensation of research activities, scientific evaluation activities, consultancy services, services, or commercial promotion, if the remuneration is proportional to the services and the compensation of costs does not exceed the costs actually incurred by the HCP;
- the donations, in cash or in kind, aimed at directly financing research activities, valorisation or scientific evaluation;
- the donations to HCP associations, provided their purpose is related to their professional activities; and
- the direct or indirect hospitality offered in the context of professional or scientific meetings, or in the context of events intended to promote healthcare products, provided that such hospitality is reasonable, limited to the purpose of the meeting or event, and limited to the HCP (to the exclusion of his/her relatives).

In such situations, a contract must be executed and either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

French law does not contain a general prohibition for pharmaceutical companies to give gifts or donations of money to healthcare organisations such as hospitals. More specifically, such gifts or donations of money to healthcare organisations are allowed. The purpose of the gift or donation must be, in principle, to sustain research or education of HCPs.

In principle, donations of equipment or funding of medical or technical services for a collective use are also allowed. There are no monetary limits. As concerns public entities, such gifts or donations must not infringe public procurement and anti-corruption rules (gifts and donations must be made independently of sales operations and must not be intended to influence procurement decisions).

In any case, the gift or donation must be formalised by a contract.

Also, it must be noted that the above-mentioned rules relating to the provision of advantages to HCPs apply. Therefore, gifts or donations to healthcare organisations are allowed if they are intended for a collective use and do not result in an individual advantage for an HCP.

For example, in the case where a pharmaceutical company purely funds a nurse, this may be critical and may entail the risk of being considered as the provision of an individual advantage to an HCP.

Also, a gift or donation to a private healthcare organisation is usually not allowed. Indeed, as HCPs are presumably shareholders of the organisation, the provision of gifts or donations could potentially be considered as an indirect benefit to the HCPs, because the cost savings for the organisation would increase the benefit and dividends accruing to the HCPs (shareholders).

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

As a general principle, Article 24 of the Professional Code for Physicians in France prohibits physicians from accepting any advantage in cash or in kind, in whatever form, directly or indirectly, as consideration for any prescription or medical act.

Therefore, such advantages can be allowed only if they do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. They must also be of a "negligible value" (as required by Article L. 1453-6, 4° of the FPHC).

More specifically, such advantages could be:

- informational or educational materials, provided they are (i) related to the practice of the medicine or the pharmacy, and (ii) for the direct benefit of the patient care; or
- items for medical use, provided they are (i) intended for the education of HCPs and for the care of the patients, and (ii) they do not reduce costs usually born by the HCPs for their day-to-day practice.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Yes, volume-related discounts to public or private organisations purchasing medicinal products are permitted by applicable rules in France. Such discounts are not considered as prohibited advertising or inducements. In this respect, Article L. 1453-6 of the FPHC specifies that such type of business advantages offered in the context of contracts governed by the provisions of the French Commercial Code ("**FCC**") are not considered as prohibited advantages within the meaning of Article L. 1453-3 of the FPHC.

In practice, such discounts must comply with commercial principles set forth in the FCC, e.g., the volume-related discount must clearly appear on the invoice.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

There are no specific restrictions regarding such extra services or equipment, provided it complies with public law when a public

institution is concerned (and in particular, public tenders procedure) or private law when a private institution is concerned (in particular, commercial, civil and competition law).

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

French law does not contain any specific regulation in this respect. However, the offering of a refund scheme if the product does not work does not seem to be allowed. This could be considered as misleading information relating to the product (i.e., suggests that the product may not work).

In this respect, the fact that the product is a prescription-only medicine or an over-the-counter medicine does not make any difference.

However, from a social security point of view, it would be far more difficult to implement such a refund scheme if the product is reimbursed by the social security schemes (in such case, the refund would have to be offered to the social security).

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes. Pursuant to Article L. 1453-7, 5° of the FPHC, the funding, or the participation to the funding, by a pharmaceutical company, of actions of continuing medical education is permitted, by derogation to the general prohibition of advantages to the HCPs.

In principle, the funds must be granted to legal entities which offer continuing medical education, for a collective use, and not to a HCP directly. In this respect, the provisions of the FPHC have been recently strengthened with the Law dated January 26, 2016 and the Ordonnance dated January 19, 2017. Pursuant to Article L. 1453-4 of the FPHC, the provision of an advantage to associations grouping HCPs, including those offering continuing medical education programmes, is subject to the general prohibition of advantages. However, in such case, a derogation exists (see question 4.2), which provides that donations to HCP associations is permitted, provided the purpose of the association is related to the professional activities of the HCPs concerned. In this case, the donation must be formalised by a contract to be declared or submitted for authorisation by the competent professional board.

In practice, a pharmaceutical company can provide funds to other types of legal entities, such as educational institutes or organisations. Although it is not specifically required by French law, it is recommended that the legal entities receiving the funds are entities duly registered with the French competent authority (the national agency for continuing professional education – the "**ANDPC**") as organisms providing medical education. In France, HCPs have to comply with compulsory and continuous educational training. To be considered compliant, they have to undergo said training sessions, which are proposed by organisations duly registered with the ANDPC. The purpose of this is to guarantee the quality of the training and the independence towards the pharmaceutical companies sponsoring or financing the organism.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The anti-bribery provisions are set out in the French Criminal Code.

Bribery is defined as unduly proposing, directly or even indirectly, offers, promises, grants, presents or advantages to a public person, either 1° to execute, or to prevent the person from executing an action in the context of his/her function, mission or mandate, or 2° in order for this person to abuse his/her influence, in the view of obtaining from a public authority or administrative body distinctions, markets or other favourable decisions.

A person that proposes, directly or even indirectly, to a private person who, in the context of his/her professional or social activities, has a director position or works for a physical person, a legal entity or any organism, offers, promises, grants or presents any advantages, for himself/herself or for other people, in the view of obtaining from him/her that he/she acts, or prevents himself/herself from acting, in violation of his/her legal, contractual or professional obligations, is also punished by the French Criminal Code.

The French authorities competent for anti-bribery practices, i.e., the "General Directorate for Competition Policy, Consumer Affairs and Fraud Control" ("*Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes*", the "**DGCCRF**") and the "**AFA**" ("*Agence française anti-corruption*") can investigate breaches to the anti-bribery rules independently from the pharmaceutical authorities.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The offering of hospitality to HCPs is governed by the anti-gift rules of the FPHC. As a derogation to the general prohibition, the offering of hospitality to HCPs is allowed. More specifically, Article L. 1453-7 of the FPHC provides that hospitality can be offered, directly or indirectly, in the context of exclusively professional or scientific meetings, or in the context of events intended to promote health products, provided the hospitality (i) is reasonable, (ii) is strictly limited to the main objective of the meeting or event, and (iii) is not extended to the HCPs' relatives.

Also, a contract must be executed in this respect and either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

It does not make any difference if the hospitality offered takes place in a foreign country. If the HCP is French, the rules applicable in France must be complied with. In principle, the contractual arrangements should be set up by the company offering the hospitality, and not the company affiliate where the hospitality takes place. In practice, however, if the HCP is French and if a company affiliate exists in France, it would make sense to involve such French affiliate in the setting up of the hospitality arrangements with the HCP, notably for the purpose of declaring or submitting for authorisation the contract to the competent board of professionals.

There are no explicit and official thresholds applicable to hospitality. However, the maximum amounts mentioned by the French medical board of professionals are commonly used as a reference:

- for accommodation: €250 in France; €325 in Paris and European capitals; and €350 in the US, Asia, Australia, Switzerland;
- for meals: €70;
- for breaks: €15 for Europe; and €25 in the US, Asia, Australia, Switzerland; and
- for transportation: 1st class train, flight in economy class up to six hours, above which business class is allowed.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

If the HCP actively participates in the scientific meeting, for example as a speaker, it is possible to pay him/her for this. In such case, a services contract must be executed between the pharmaceutical company and the HCP, and be either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

On the other hand, it is not possible to pay a HCP if he/she is just attending the meeting, passively (e.g., to pay him/her for his/her time). In such case, however, the pharmaceutical company can offer him/her hospitality, under the conditions and within the limits above-mentioned.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Pharmaceutical companies may be held responsible for the contents of scientific meetings organised by the company. It is also the case in the context of scientific meetings, except if it can be proven that the content of the presentations was exclusively non-promotional (which may be difficult in practice). As an example, if off-label information is provided during a meeting organised or sponsored by a company (and if it cannot be proven that the meeting was exclusively non-promotional), the company may be held responsible for the presentation of off-label information in the context of promotional presentations.

However, a pharmaceutical company will not be held responsible for the contents of a scientific meeting if it has only offered hospitality to HCPs attending the meeting, but has not organised nor sponsored such meeting.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes, it is possible to pay HCPs to provide expert services (e.g., participating in advisory boards), under certain conditions.

Pursuant to Articles L. 1453-7 *et seq*. of the FPHC, it is possible to pay HCPs for research activities, scientific evaluation activities, consultancy services, services, or commercial promotion services, if the remuneration is proportional to the services and the compensation or expenses do not exceed the costs actually incurred by the HCP.

Also, a contract must be executed and specify the services concerned. Such contract must be either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

In addition to those principles, the Ethical professional provisions issued by the LEEM specify supplementary principles that must be complied with and provisions that must be inserted in the contract with the HCP. Among those principles, the LEEM indicates that:

- the services must correspond to a precise legitimate need, clearly identified by the company before the conclusion of the contract;
- selection criteria of the experts are related to the said identified need of the company and the employees in charge of their selection are competent to check whether these criteria are complied with or not;
- the number of experts shall not exceed the number of participants reasonably necessary to meet the identified need;
- the company keeps records of the documentation relating to the services and makes appropriate use of the services;
- the solicitation of the HCPs for the services does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products; and
- remuneration is reasonable and corresponds to the fair market value of the services provided.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes, it is possible to pay HCPs to take part in post-marketing surveillance studies. In such case, Articles L. 1453-7 *et seq*. of the FPHC shall apply (see question 5.4).

In addition to those principles, the ethical professional provisions issued by the LEEM also specify supplementary principles that must be complied with, and notably:

- the study shall pursue a scientific objective;
- there must be (i) a study plan/protocol, and (ii) written contracts between, on the one hand, HCPs and/or institutions where the study is conducted and, on the other hand, the company which is a sponsor of the study, specifying the services to be rendered;
- the remuneration, if any, shall be reasonable and correspond to the fair market value of the services;

- the study shall comply with applicable laws and regulations relating to data protection;
- the study shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products;
- the study protocol shall be approved and managed by the scientific department of the company;
- the study results shall be analysed by or on behalf of the company and reports shall be provided to the scientific department of the company, which shall keep records of these documents for a reasonable period of time. The company shall send the documents to all HCPs participating in the study and, upon request, to competent authorities. If the results have a subsequent importance for the benefits/risks evaluation, the report summary shall be sent to the concerned competent authority; and
- the sales representatives shall not take part in the implementation of these studies.

### 5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Yes, it is possible to pay HCPs to take part in market research involving promotional materials. In such case, the same rules and principles as those mentioned in question 5.4 apply.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes, it is possible to advertise non-prescription medicinal products to the general public, provided none of the different presentations of such medicinal products are reimbursed by the French social security schemes and provided that the marketing authorisation of the medicinal product does not contain any restriction nor prohibition regarding advertising to the general public due to a potential risk for public health, notably if the use of the medicinal product is dependent upon the HCP's intervention for diagnostic, initiation or surveillance of the treatment (Article L. 5122-6 of the FPHC).

The promotional character of the advertising must be obvious, and the medicinal product shall be clearly identified as a medicinal product.

Pursuant to Article R. 5122-3 of the FPHC, the advertisement shall contain, at least, the following information:

- the name of the medicinal product, as well as the INN;
- the necessary information for a proper use;
- the express invitation to read carefully the instructions mentioned on the notice or on the package, as the case may be;
- a word of caution, an invitation to talk to a pharmacist and, if the symptoms persist, an incentive to consult a doctor; and
- the mention of the generic character of the product, as the case may be, together with additional information.

Please note that, pursuant to Article R. 5122-4 of the FPHC, the advertisement cannot contain certain specific allegations, e.g., that the benefit of the medicinal product is guaranteed.

As indicated, any advertisement to the general public is subject to the prior obtaining of the "visa" from the ANSM (see question 1.5).

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No, it is not possible to advertise prescription-only medicinal products to the general public, except in some limited cases: advertising for anti-tobacco medicinal products or vaccines, that are subject to prescription; and/or reimbursable by the French social security schemes, is possible under certain conditions (provided in Articles L. 5122-6 and L. 5122-8 of the FPHC).

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Yes, such disease awareness campaigns are permitted, provided they do not contain any direct or indirect reference to a medicinal product (Article L. 5122-1 of the FPHC). Indeed, the FPHC excludes from the definition of "promotion" the release of information related to human health or human diseases, as soon as there is no reference, even indirectly, to any medicine.

Pursuant to the recommendations issued by the ANSM, such non-promotional information can mention, on a non-exclusive basis, the therapies available, whether of medicinal nature or not. The therapeutic classes (from the ATC classification system) can be mentioned provided they contain more than one medicinal product.

### 6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

There are no specific prohibitions in France which prohibit the issuance of press releases concerning prescription-only medicinal products to non-scientific journals. However, such press releases are allowed, provided they have informative purposes and they are not intended, in practice, to promote a specific medicinal product.

On this subject, the Court of Appeal of Versailles pointed out that the fact that the information is provided during a press release does not exclude a potential promotional character. However, the promotional intention of the company has to be evidenced. In this respect, attention has to be paid to the lyrical style employed and any allegations, as the case may be (Court of Appeal of Versailles, June 25, 2014, N. 14/03658).

If the press release does not constitute advertising, it is not specifically prohibited for it to refer to developments in relation to as yet unauthorised medicinal products or unauthorised indications. However, press releases must be made with extreme caution to ensure that they cannot be considered as promotional.

### 6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Restrictions that apply to advertising do not apply to information documents of a scientific, technical or financial character, issued by the company, provided they are not promotional (Article R. 5124-67 of the FPHC).

ANSM refers to this information as "institutional information". In its recommendations, the ANSM indicates which information can be mentioned in this context:

- the name of the medicinal product;
- the INN; and
- the therapeutic class.

According to the ANSM, any other information related to the medicinal product would be deemed as promotional, in particular the therapeutic indication, posology, method of administration, contraindications, tolerability, adverse effects, pictures of dosage forms and packaging.

Similarly, every term with a reference to a hierarchy, such as "leader", "first", "best", "number 1", "the only one", qualifying a medicinal product, may be used only if these qualifiers refer to the turnover, market share, quantities sold, etc. Such qualifiers may not be used if they refer to a comparative evaluation of therapeutic benefits of a treatment or medicinal product.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There are no specific legal provisions in France which govern the meeting with, and the funding of patient organisations. As a general principle, the provisions of the FPHC governing the promotion of medicinal products, and notably the prohibition of advertising of prescription-only and/or reimbursed medicinal products to the general public, apply to the relationship between the pharmaceutical industry and patient organisations.

There are additional requirements set out in the "Ethical professional provisions" ("*Disposition déontologiques professionnelles*") issued by the LEEM. Cooperation between the pharmaceutical industry and patient organisations, as well as their funding by the pharmaceutical industry, is possible provided certain principles are complied with. If a pharmaceutical company provides financial support to a patient organisation, a written agreement is required, which shall mention notably the amount provided and the purposes of the support. It shall also detail the indirect and non-financial support. Also, the pharmaceutical companies have to stay neutral and respect the organisation's independence. The collaboration has to be conducted in a transparent and open manner. Also, such collaboration must not entail any promotion of prescription-only and/or reimbursed medicinal products.

According to the above "ethical professional provisions", pharmaceutical companies must also disclose publicly all financial and non-financial supports provided to patient organisations.

Regarding hospitality, similar principles as those governing hospitality to HCPs apply (e.g., the hospitality must be reasonable, strictly limited to the main objective of the event, and not extended to the relatives of the patient organisation).

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Free samples of medicinal products cannot be provided for a promotional purpose to the general public (Article L. 5122-10 of the FPHC).

Also, pursuant to Article R. 5122-4 of the FPHC, the advertising of medicinal products to the general public shall not contain any direct or indirect offer of objects, products or material advantages.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Pursuant to Article L. 1121-15 of the FPHC, information/details relating to clinical trials authorised by the ANSM have to be disclosed on a national database (register).

All clinical trials shall be registered before the study starts.

The "*Arrêté du 9 décembre 2008 fixant le contenu du répertoire des recherches biomédicales autorisées portant sur des médicaments à usage humain*" as of December 9, 2008, lists the information that the register must contain. Among others, the register must contain the title of the clinical trial, the EudraCT number, details on the sponsor, a description of the clinical trial as well as some details on the investigational medical product.

The sponsor of the clinical trial can refuse to make publicly available some of the information requested if it considers that such disclosure is likely to prejudice its legitimate interests, notably regarding confidentiality. According to the above-mentioned *Arrêté*, the information that a company may refuse to make publicly available are: the complete title of the trial; the main secondary objectives, if any; and the number of participants expected in France or the number of participants expected in the countries where the clinical trial is conducted.

According to the above *Arrêté*, the register must also disclose, within one year from the end of the clinical trial, the overall results of the research.

In practice, this register is available on the website of the ANSM, which contains a link to the EU clinical trials database.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Yes, Article L. 1453-1 of the FPHC provides for the obligation for companies to make publicly available, on a public website (transparency central platform), the following information relating to the agreements concluded with, among others, HCPs, associations of HCPs, patient organisations and healthcare institutions:

- the specific purpose of the agreement;
- the date of the agreement;
- the direct and final beneficiary; and
- the amount of the agreement.

Also, companies shall make publicly available on the above-mentioned public website any transfer of value (remuneration or direct or indirect advantage) exceeding €10 granted to the above-mentioned persons/entities (e.g., HCPs, associations of HCPs, patient organisations, healthcare institutions) (Articles L. 1453-1 and D. 1453-1 of the FPHC).

All companies manufacturing or commercialising health products or executing related services are concerned by this requirement, regardless of whether they are settled in France or not and regardless of whether their products are commercialised in France or not, as long as they have a relationship with the above-mentioned French persons/entities (e.g., French HCPs, French associations of HCPs, French patient organisations, French healthcare institutions (*Circulaire* issued by the French Direction Générale de la Santé, see http://circulaires.legifrance.gouv.fr/pdf/2017/06/cir_42320.pdf).

The companies shall declare such information on the public website no later than (i) September 1 of each year, for agreements concluded or transfers or value granted during the first semester of the year, and (ii) no later than March 1 of each year, for agreements concluded or transfers of value granted during the second semester of the year.

### 7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

The EFPIA "Disclosure Code" (binding on the member companies of the LEEM) requires companies to disclose transfers of value made to HCPs or to healthcare organisations. Such disclosure shall be made every year by June 30 for payments made the year before (e.g., by June 30, 2019 for payments made in 2018), either on the company's websites or on a central platform (Section 2.04 of the EFPIA "Disclosure Code").

Since French legislation already provides for a specific central platform dedicated to the disclosure of transfers of value, the disclosure of such information on the companies' websites is not required.

### 7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Since the above-mentioned publication of transfers of value is a legal requirement, HCPs cannot object to such publication. Moreover, French legislation does not provide for any obligation for the company to obtain the consent of HCPs for the publication of their information, not for any right of objection in favour of HCPs. In practice, companies must, however, inform HCPs of this publication, in accordance with applicable laws and regulations relating to data protection (i.e., notably the General Data Protection Regulation). This information is usually provided by a clause in the contract signed between the company and the HCP.

## 8 The Internet

### 8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The advertising of medicinal products on the Internet is subject to the rules governing the advertising of medicinal products in general (please see section 7 above). Internet advertising is also regulated by the "Charter for the communication and the promotion of health products on the Internet and e-media" ("*Charte pour la communication et la promotion des produits de santé (médicaments et dispositifs médicaux) sur Internet et le e-media*") issued by the ANSM.

This Charter aims notably to help companies design and process their websites in accordance with the principles relating to the advertising of health products.

As a general principle, the website must particularly identify the processor of the website, the intended recipients and the type of information provided. Also, the website must be regularly updated and mention clearly the last update, and the advertisements must be clearly identified (the promotional character can be either deducted from the specific promotional format of the website page, or specified with a written mention if the promotional character is not obvious).

More specifically, the structure of the website must comply with the rules governing the advertising of medicinal products, e.g., provisions relating to the prohibition of the promotion to the general public of certain medicinal products (prescription-only and/or reimbursed medicinal products). As a consequence, advertisements intended for HCPs must be displayed on web pages accessible to HCPs only.

The advertisement must contain the mandatory information required by the FPHC in relation to the medicinal product concerned (see question 3.1). They shall be immediately apparent and the size of the characters shall not be smaller than the smallest characters used for promotional statements.

The relevant authorisation ("visa") must be obtained from the ANSM before the advertisement is put online (see question 1.5).

The Charter for the communication and the promotion of health products on the Internet and e-media also requires websites to clearly separate the promotional section of the website from other sections, such as, for example, those relating to "institutional information" (see questions 6.5) or those containing information relating to human health or human disease (which is not deemed promotional, provided there is no reference, even indirectly, to a medicinal product).

### 8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

Pursuant to the "Charter for the communication and the promotion of health products on the Internet and e-media", genuine restrictions of access have to be implemented by companies to ensure that members of the general public do not have access to sections of websites intended for HCPs.

This Charter is not very specific in this respect, but it provides that, as an example, an access code can be granted to the HCP once the company has been able to duly confirm his/her statute of HCP, via the fulfillment of an electronic form or by the registration and/or identification of the HCP by means of his/her professional number.

In any case, the mere confirmation by the user that he/she is a HCP is not sufficient.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Pursuant to the "Charter for the communication and the promotion of health products on the Internet and e-media", a link from a company-sponsored website to an independent website shall not aim at circumventing the rules governing advertising of medicinal products. Companies will be responsible for any such link that would circumvent applicable rules. In that respect, a company may be held responsible due to the content of the independent website.

The Charter distinguishes the "simple link", which gives access to the homepage of a website, from the "deep link", which gives access to a subpage. As a general principle, a "deep link" may be used for every public official website page. In this respect, the Charter also provides for specific recommendations relating to peer-reviewed journals' or congresses' websites.

In any event, the transition from one website to the other shall be obvious for the user (either by a message of information, or by opening a new tab).

If the linked websites are restricted to HCPs, the access codes or other security system employed cannot, in any event, be provided by the initial website. Every website shall manage its own security system, with specific access codes, unless the linked websites benefit from a common authentication system.

Reverse linking is not specifically addressed by the above-mentioned Charter. However, the principles of the said Charter shall apply.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Medicinal products for which advertising to the general public is allowed can be advertised on a website which is accessible to the general public, provided such advertising complies with the applicable requirements (see question 6.1).

Also, a website accessible to the general public can contain information which is not considered as promotional, e.g., "institutional information" (see questions 6.5), or information relating to human health or human diseases, provided such information does not contain any reference, even indirectly, to a medicinal product (see question 1.2), or concrete information and reference documents related, for example, to packaging modifications, warnings concerning adverse effects identified in the context of pharmacovigilance, and sales catalogues and price lists, provided they do not contain any information on the medicinal product (see question 1.2).

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

According to the "Charter for the communication and the promotion of health products on the Internet and e-media", the use of the "like" button of social networks such as a Facebook page relating to a medicinal product may be interpreted as a claim of recovery by the general public or as a validation by a HCP. It shall therefore be considered as not compliant with the provisions of the FPHC.

Therefore, the promotion of the medicinal products via social media shall be considered as not allowed, unless these options (such as the "like" button) can be deactivated.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

The significant developments that have occurred in recent years concern the anti-gifts provisions, which have been modified recently by a Law dated January 26, 2016 and by an Ordonnance dated January 19, 2017 and which are now set out in Articles L. 1453-3 *et seq*. of the FPHC. Such new provisions have entered into effect on July 1, 2018, except for the provisions which need the publication of an implementation decree.

The purpose of these provisions is to strengthen and to broaden the scope of the anti-gifts regulations (see question 4.2).

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

To date (May 2019), an implementation decree is expected to specify notably the process applicable to the contracts and relationship between pharmaceutical companies and HCPs (and other stakeholders). For example, contracts must now be executed and either (i) declared, or (ii) submitted for prior authorisation (depending on the amount at stake) to the competent board of professionals.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

No, there are no general practice or enforcement trends that have become apparent in France.

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MERCURE AVOCATS

Mercure Avocats is a law firm specialised in business law with strong expertise in the field of pharmaceutical law/life sciences. The founders of Mercure Avocats were trained in one of the most reputed international law firms in the field of life sciences. Mercure Avocats has developed expertise in regulations in life sciences, in the pharma, cosmetics, food products and associated technology sectors. Mercure Avocats also specialises in preparing and negotiating all types of contracts specific to the healthcare sector (e.g., R&D contracts, licence agreements, contracts with HCPs, etc.). Thanks to the "human size" of the firm, the files are directly handled by the partners and the team is committed to working intimately with clients in order to find solutions fitting to their individual challenges, in a long-term relationship. Mercure Avocats strives to offer flexible working methods and to implement pragmatic solutions taking into account its clients' operational/business constraints.

# Germany

Dr. Peter Dieners

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Clifford Chance

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Advertising of medicinal products is governed by the Law on Advertising in the Field of Healthcare (*Heilmittelwerbegesetz – HWG*), last amended on 20 December 2016. In addition, the provisions of the Law against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb – UWG*), last amended on 17 February 2016, must be observed.

With regard to advertising to healthcare professionals, a large part of the industry agreed to comply with the FSA-Code of Conduct on the Collaboration with Healthcare Professionals (FSA-Code of Conduct Healthcare Professionals) of the Organisation "Voluntary Self-regulation of the Pharmaceutical Industry" (*Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. – FSA*), which was last amended with effect as of January 2018 (FSA-Code of Conduct Healthcare Professionals). The FSA-Code of Conduct Healthcare Professionals takes into account, in particular, the "Common Position of the Assessment in Criminal Law of the Cooperation between Industry, Medical Institutions, and their Employees" (Common Position), which was published in October 2000 by the major trade associations and other organisations in the healthcare sector, as well as the Model Professional Rules for German Physicians issued by the German Federal Chamber of Physicians. The FSA-Code of Conduct Healthcare Professionals was revised in December 2013 in order to reflect the requirements of the EFPIA Code of Practice on the Promotion of Prescription-only Medicines to, and Interactions, with Healthcare Professionals, issued by the European Federation of Pharmaceutical Industries' Associations (EFPIA) (EFPIA-Code of Conduct). Furthermore, the FSA adopted a Code of Conduct on the Collaboration with Patient Organisations (FSA-Code of Conduct Patient Organisations), which became effective on 15 October 2008 (last amended in 2011). The FSA-Code of Conduct Patient Organisations implements the respective EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations. With the objective of structuring collaboration with patient organisations in accordance with the principles of neutrality and independence, the FSA-Code of Conduct Patient Organisations also makes it clear that such collaboration should not be used in a manner to circumvent the laws prohibiting the advertising of prescription-only medicines. The FSA Recommendations on the Collaboration of the Pharmaceutical Industry with Partners in the Healthcare System and their Employees were published in December 2010. The recommendations include specific guidelines on the interaction between the pharmaceutical industry and other decision-makers in the healthcare sector. The Recommendations have been amended in December 2014. Furthermore, in December 2013 the General Assembly of the FSA adopted a FSA Transparency Code (for further details please refer to questions 7.2 and 7.3 below).

In November 2007, another self-regulatory organisation, "Pharmaceuticals and Cooperation in the Health Care Sector" (*Arzneimittel und Kooperation im Gesundheitswesen e.V. – AKG*), was founded and became active as of 1 January 2008. The AKG implemented the AKG-Code of Conduct (*AKG-Verhaltenskodex*), which is binding for its member companies and was last amended on 22 April 2015.

As to the provisions relating to the collaboration between the industry and physicians, the content of the FSA-Code of Conduct Healthcare Professionals and the AKG-Code of Conduct are also based on the Recommendations of the collaboration of physicians issued by the German Association of Research-based Pharmaceutical Companies (VFA), the German Federal Association of Pharmaceutical Manufacturers (BAH) and the German Association of the Pharmaceutical Industry (BPI) in July 2003. While the Recommendations have no legal force, the conduct requirements of the FSA-Code of Conduct Healthcare Professionals are binding on member companies of the FSA and monitored and sanctioned by the FSA. The same applies to the AKG-Code of Conduct, which is monitored and sanctioned by the AKG.

### 1.2 How is "advertising" defined?

The HWG does not provide a definition for "advertising". According to the case law of the German civil courts, the term "advertising" implies any kind of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of a specific pharmaceutical product. Therefore, almost all information which is published by a pharmaceutical company to the general public or to third parties is very likely to be classified as "advertising".

However, German law differentiates between so-called "product advertising" and "image advertising". Product advertising means advertising of a specific product, while image advertising is characterised by advertising with the name of the pharmaceutical company or the entire range of products without any reference to a specific product. "Image advertising" is not subject to the rules of the HWG.

**1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?**

Section 74a of the German Drug Act (*Arzneimittelgesetz – AMG*) stipulates that any person who, as a pharmaceutical entrepreneur, places medicinal products on the market, shall appoint an information officer who is responsible for ensuring that the labelling, the package leaflets, the expert information and advertisements correspond with the content of the marketing authorisation.

Besides this legal requirement, there are no further direct arrangements companies must have in place. Against this background, the creation of internal arrangements stipulating a "sign-off" of promotional campaigns and/or documents can be helpful with regard to the control of documents and material published by the company. In this regard, it should be taken into account that a company is also liable for the activities and conduct of its employees, agents, etc., even where the company did not have any knowledge of the individual activity or conduct of the employee, agent, etc. Therefore, the control and supervision of advertising material prior to its publication is recommendable to satisfy the legal requirements and to avoid any liability for violating content published by employees, agents, etc.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

As described above (question 1.3), pursuant to Section 74a of the German Drug Act (*Arzneimittelgesetz – AMG*), a pharmaceutical entrepreneur shall appoint an information officer. The person commissioned with this task shall have the necessary expert knowledge and the reliability required to perform his/her activities and to responsibly fulfil the task of providing scientific information on the medicinal products.

There are no explicit legal or code requirements for companies to establish Standard Operating Procedures (SOPs) regarding advertising activities. However, the provision of such SOPs is advisable due to the general obligation to introduce appropriate rules and proceedings as part of the overall compliance organisation. Particularly in the context of advertising activities, relevant SOPs are important since advertising activities also cover interactions with healthcare professionals which are subject to various legal risks, including criminal liability. Therefore, the respective procedures should cover relevant laws and regulations to ensure conformity of the advertising activities with the applicable advertising provisions. All working steps should be described in detail and a proper documentation of the review and release process should be in place. Companies should also define clear responsibilities of employees in order to optimise working structures.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

Advertising for medicinal products does not need to be approved in general or in specific circumstances. Furthermore, there is no obligation in Germany to provide competent authorities with advertising material.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

If a competent authority considers an advertisement to be unlawful, it has the power to stop further publication of such advertisement. However, authorities have no legal power to force a pharmaceutical company to publish a corrective statement. A pharmaceutical company which has been subject to such administrative measures by the competent authorities has various rights of appeal. It can file an objection to the decision since such decisions by competent authorities are considered to be administrative acts. If the objection has not been successful, a company can file a lawsuit before the competent administrative courts.

However, prohibition of advertisements by competent authorities is very rare in practice. Usually, competitors take action directly through the civil courts and seek to obtain injunctive relief against unlawful advertisements (see questions 1.7 and 1.9).

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The intentional breach of the regulations of the HWG on misleading advertising constitutes a criminal offence punishable by an imprisonment for a term of up to one year or by a fine. The negligent breach of these regulations may be punished by an administrative fine of up to EUR 20,000. All other intentional or negligent breaches of explicitly listed regulations of the HWG may result in fines of up to EUR 50,000. However, in practice, infringements of the regulations of the HWG are only prosecuted in exceptional cases. Furthermore, administrative fines are only imposed in rare cases where such infringements have a severe impact on patients or public health.

The public prosecution authorities investigate criminal offences and bring them before a criminal court. The responsibility of imposing and enforcing regulatory fines lies with the relevant competent authorities who are responsible for the administrative supervision of the pharmaceutical company in question. Both bodies have the option to refrain from investigation or punishment in the case of minor infringements.

More importantly, competitors may take direct action through civil court procedures. They generally seek injunctive relief to stop advertisements violating their rights on the basis of the UWG. The competitor's main focus hereby lies on cease-and-desist declarations with a penalty clause to prevent further advertisement violations. In addition, competitors may claim further remedies including damages in substantive proceedings.

Apart from the judicial sanctions noted above, a breach of the regulations of the HWG on misleading advertising may, provided that a member company of the FSA committed the infringement, also result in a sanction by this organisation. The monitoring and sanctioning of the conduct requirements is the responsibility of the FSA's arbitrators, who can impose fines of at least EUR 5,000 to

EUR 400,000. The FSA, as an association promoting commercial interests, is also competent to take action in civil proceedings against non-members of the FSA under the provisions of the UWG.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

In principle, the decisions or other measures of self-regulatory bodies (e.g. the arbitration body of the FSA in Germany) do not have any legal impact on the potential actions of German competent authorities. Consequently, a German competent authority may investigate matters that require interpretation of both the law and the relevant code, even though the arbitration body of the FSA has previously assessed such matters and has rendered a decision. There are currently no reported instances where the competent authorities have, in practice, investigated such matters.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

As a breach of a rule within the HWG is automatically considered unlawful under the UWG and as the HWG does not (itself) provide for a right to an injunction, it is possible to seek remedies directly through the civil courts.

Action can be taken in order to seek injunctive relief, as well as to seize the illegal advertising material. However, such actions may be taken only by direct competitors, associations promoting commercial interests (*Wettbewerbsvereine*), and consumer associations. Industry and Commercial Chambers are also entitled to such claims. A claimant can request a corrective statement or the communication or publication of the judgment to third parties. Apart from this, a claimant can also sue for damages and compensation, and can request an account of any profit made.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

The HWG is applicable to the advertising of a specific medicinal product (product-related advertising), but does not cover the provision of image advertising (see above, question 1.2) or general information. Pursuant to the HWG, any advertising activity concerning a specific medicinal product is only permissible if it has obtained the relevant marketing authorisation or registration. Any advertising of unauthorised or unregistered products during the development phase is generally considered to be unlawful. Such pre-marketing sales promotion activities constitute an infringement of the HWG. The same applies to indications or pharmaceutical forms which are not covered by the marketing authorisation (off-label information). Companies may not make public displays of off-label information at German national meetings.

However, the exchange of medical and scientific information during the development or marketing authorisation phases of a medicinal product is permissible, provided that such activities are not considered to be part of product-related advertising. Therefore, scientific information material such as copies of reports on the outcome of clinical studies, or scientific speeches and publications, may be made available at scientific meetings or conferences by mentioning the non-proprietary name of the active ingredient(s) (INN), provided that the anticipated new product name is not mentioned or otherwise identified.

Consequently, the risk of infringement of the HWG is higher the more such scientific information relates to a specific product or product trademark, or is used in relation to the advertising activities for an unauthorised product.

Companies may issue factual scientific information regarding unlicensed medicinal products or indications only in response to unsolicited inquiries by healthcare professionals. Responding to such unsolicited questions regarding a specific medicinal product is not considered as promotion, but as company-related information. However, the off-label information provided in response should not go beyond the scope of the question.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Publications relating to unauthorised medicinal products or to indications or pharmaceutical forms which are not covered by the marketing authorisation must not be of a promotional nature (see question 2.1). Articles in scientific journals which comply with the conditions outlined in question 2.1 above are permissible.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

It is permissible to inform the media about medicinal products which have not yet been authorised or registered, as well as about indications or pharmaceutical forms which are not covered by the marketing authorisation, provided that the conditions noted in question 2.1 above are fulfilled. However, press releases are most likely to be considered promotional (and therefore, unlawful) where the anticipated new product name is mentioned. An exception may, however, be made where such information is not intended to promote the medicinal product itself, but where it is necessary to understand the economic and financial position of the company, i.e. when informing on certain development milestones which have been reached. In this case, the press release must be drafted in such a way that it cannot be considered as an advertising tool. The cumulative effect of using marketing materials or advertising slogans, or making exaggerated, ambiguous or incomplete claims may lead to the press release being characterised as promotional. It is, in any case, not permissible to pay or grant incentives for the publication of a press release or an article written on the basis of such press release.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Unsolicited information, as well as material sent upon request, will be considered as a (prohibited) advertisement if the company distributed the information within its product promotion. Such communication may only be lawfully performed if the active substance itself is mentioned and the brand name of the product is not mentioned in or is not easily deductible from the information provided.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

In 2012, Section 1 and Section 8 of the HWG have been amended to reflect the ECJ judgment. In Section 1 HWG, a new paragraph 7 has been added: "This act shall further not apply to trade catalogues and price lists to medicinal products, which contain no other information than the necessary ones to identify the medicinal products." Moreover, additional wording has been included in Section 8 HWG: "Unless, it applies to the distribution to pharmacists of lists of non-approved medicinal products, the importation of which from another Member State or a non-Member State which is a party to the Agreement on the European Economic Area is authorised only on an exceptional basis, which contain no information other than that concerning the trade name, packaging size, dose and price of those medicinal products."

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Institutions may be provided with such information so long as the rules noted in question 2.1 (above) are met. However, it may be difficult in practice to avoid unlawfully promoting such information.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Healthcare professionals may be involved in market research exercises relating to such marketing materials provided that the involvement cannot be deemed to circumvent prohibition against promoting unauthorised medicinal products or indications. Consequently, the involvement of healthcare professionals should not be misused to promote the unauthorised medicinal product or a new indication which has not yet been included in the marketing authorisation. Furthermore, the rules for contractual cooperation with healthcare professionals as set forth in questions 5.4 and 5.6 must be met. No guidelines on market research have been published to date.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Advertising to healthcare professionals, including claims for use of a medicinal product, must contain the following mandatory information:

a) the name or company and permanent address of the pharmaceutical company;

b) the name of the medicinal product;

c) the composition of the medicinal product;

d) the therapeutic indication(s);

e) contraindications;

f) side effects;

g) specific precautions for use insofar as these are required for the labelling of containers and outer packaging; and

h) for medicinal products that can be obtained only on prescription, with the marking "prescription only" (*verschreibungspflichtig*).

In addition, the FSA-Code of Conduct Healthcare Professionals requires that the member companies of the FSA must also specify the date on which such information was granted or last revised.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Medicinal products must not be promoted before the required marketing authorisation is obtained (Section 3a HWG). Furthermore, advertising of prescription-only medicinal products to patients is prohibited (Section 10 HWG).

The following promotional activities, amongst others, are prohibited:

- Misleading advertising.
- Gifts and other advertising giveaways.
- Promotional activities aimed at the general public must not contain any advertising statements relating to prescription-only medicinal products or to (severe) diseases explicitly mentioned in the Healthcare Advertising Act.

Further regulations prohibit marketing activities using, for example, expert opinions, certain illustrations or samples. These additional requirements do not apply to advertising activities which are only aimed at healthcare professionals.

It is only permissible to refer to studies not referred to in the SmPC if such studies are not contradictory to each other and meet certain scientific standards. In addition, it would not be allowed to refer to a study on an off-label indication (Section 3a HWG).

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Pursuant to Section 11 HWG, an advertisement addressed to the general public (i.e. not restricted to a healthcare professional) must not contain recommendations by scientists and/or healthcare professionals.

Furthermore, according to the (Model) Professional Code for Physicians in Germany (*Musterberufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte – MBO-Ä*) (Section 27 (3) MBO-Ä), physicians must not advertise their own commercial

activities or products, or the commercial activities or products of others in connection with professional activities. This conduct has been prohibited since promotional activity for pharmaceutical companies can lead to an economic reliance of physicians or to a change in their prescription practice. However, physicians are allowed to give lectures or render expert opinions on the aforementioned products for non-promotional reasons.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There is no explicit written requirement under German law. However, according to one of the key principles, advertising must not be misleading which means that any claim made has to be scientifically substantiated. With regard to comparative claims, courts consider such substantiation as generally sufficient if they are based on "head to head" clinical trials.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Comparisons with the medicinal products of competitors are only permissible with respect to advertisements to healthcare professionals; such comparative advertising is not allowed to the general public. Comparative advertising to healthcare professionals must not be misleading and the compared products must be similar. However, such comparisons have to compare relevant, verifiable and typical characteristics of the products concerned, such as their prices and active ingredients. Otherwise, the comparison may be misleading and, therefore, unfair under the rules of the German Act against Unfair Competition.

To the extent that the requirements of the German Act against Unfair Competition are met, the competitor's brand name or trademark may be used as part of the comparison, provided that the comparison does not include any biased or disparaging statements about the competitor.

Please note that in comparative advertisements it is not permissible to refer to a competitor's product or indication which has not yet been authorised in Germany.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no specific rules for the distribution of scientific papers to doctors and/or proceedings of congresses.

According to the general rules, such material relating to medicinal products (which have already obtained a marketing authorisation) may, for example, be provided to physicians attending a medical conference as part of the conference documentation.

Besides distribution at an occasion such as an educational event, such materials may be given to doctors if they satisfy the limited number of exceptional rules for gifts (see question 4.2). If the scientific papers and/or proceedings of congresses relate to a non-authorised pharmaceutical, the rules explained above (see question 2.1) apply.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

German advertising law for medicinal products does not provide for any specific regulation relating to "teaser" advertisements. Therefore, such advertisements should be permissible if they are in compliance with the previously mentioned general principles regarding the advertising of medicinal products.

However, according to these general principles, each advertisement for medicinal products that is to be considered "product advertising" within the meaning of the HWG (see question 1.2 above) has to provide certain information on the medicinal product, Section 4 HWG (see question 3.1). As the nature of "teaser" advertising suggests, if neither the name of the medicinal product, nor the name of the pharmaceutical company, are mentioned in order to arouse the reader's curiosity, such "teaser" advertisements are impermissible under the HWG. If such "teaser" advertising is considered "image advertising" within the meaning of the HWG (see question 1.2), information related to the medicinal product (see question 3.1) need not be provided, as such "image advertising" is not subject to the rules of the HWG (see question 1.2). Such "teaser" advertisements are, therefore, permissible if the general provisions for all advertisements are met, including that the advertisement may not be misleading.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

As a general rule, medicinal products must not be promoted outside the scope of its marketing authorisation (see question 2.1). Such scope is defined in further detail by the SmPC, which is reviewed and approved by the competent regulatory authority. Each marketing authorisation is, by its nature, company-related and its authorising effect is limited to its holder. Thus, as a general principle, any medicinal product may only be promoted by the holder of and within the scope of the respective marketing authorisation, even though the product may be identical to another product with a different (broader) label.

Against this background, it would be possible for the holder of the marketing authorisation of Product A to promote Product A for combined use with Product B. Conversely, however, it would not be possible for the holder of the marketing authorisation of Product B to promote such combined use of Product B as no such marketing authorisation for Product B exists until the marketing authorisation/SmPC is amended accordingly.

As stated above (see also question 2.1), it would still be possible to refer to the existing marketing authorisation for combined use as a response to an explicit and unsolicited request by a third party, as such communication is privileged under the HWG.

## 4 Gifts and Financial Incentives

### 4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

The provision of samples of medicinal products is limited according to Section 47 paras 3 and 4 of the German Drug Act (*Arzneimittelgesetz – AMG*). Healthcare professionals may be provided with samples of medicinal products for informational purposes, but only in small numbers and upon their written request. The supply of such samples must be recorded by the company. Samples may be provided to healthcare professionals and to healthcare training institutions, with a maximum amount of two packages per year. The packages must be of the smallest commercially available size or may be specially manufactured sample packages with even less content. Furthermore, they must be labelled as samples, i.e. the labelling must indicate that they are not for sale. In addition, samples may only be provided if they are accompanied by a professional information sheet according to Section 11a AMG.

Stricter regulations apply for member companies of the FSA. According to Section 15 FSA-Code of Conduct Healthcare Professionals, medical samples may only be supplied to a healthcare professional for a limited period of two years after the initial request by each healthcare professional. The number of medical samples is limited to two samples per year. In this context, a new medicine is a product for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following a major change of the marketing authorisation or an extension (considering Appendix II Nr. 2 lit a) or Appendix I No. 2 of the regulation (EG) Nr. 1234/2008). For pharmaceuticals which have been placed on the market before 31 December 2011, the first request of a medical sample by each healthcare professional after 31 December 2011 is considered to be the first request.

### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

In principle, the HWG does not allow the offer or supply of gifts or other benefits, or the acceptance of such gifts or benefits. In addition, the Professional Rules for German Physicians prohibit the acceptance of any gifts or benefits which might influence their prescribing or therapeutic decisions, or which could be considered as a reward for such previous decisions. Furthermore, the FSA-Code of Conduct Healthcare Professionals and German criminal law generally prohibit the provision and acceptance of any kind of benefits with respect to hospital physicians which are granted in the context of their work, especially as consideration for carrying out purchasing or prescription decisions (see question 4.3). In June 2016, by virtue of the new anti-corruption law in the healthcare sector (*Gesetz zur Bekämpfung von Korruption im Gesundheitswesen*) implementing the new Sections 299a and 299b of the German Criminal Code, this criminal liability has been extended to private practitioners. According to these new rules it is prohibited to offer, promise or grant a benefit to someone in connection with the exercise of his/her profession, if he/she belongs to a medical profession that requires government-regulated training in order to practice the profession or to carry the professional title, for himself/herself or for a third person so that he/she prefers the grantor or another person in an unfair manner in the domestic or foreign competition in the context of (i) prescribing pharmaceuticals, remedies, adjuvants or medical devices, (ii) obtaining pharmaceuticals, adjuvants or medical devices, which are intended for direct application on the patient by the healthcare professional or his assistant, or (iii) referral of patients or examination material as a consideration for being offered, promised or granted the benefit.

The FSA-Code of Conduct is even stricter and prohibits the promise, offer or granting of gifts to healthcare professionals (irrespective of product-related or non-product-related advertising). According to Section 15a FSA-Code of Conduct, member companies may only provide healthcare professionals with:

(i) Informational and educational materials. Such materials must be inexpensive, have a direct connection with the professional activity of the healthcare professional and be genuinely linked with patients' care.

(ii) Items of medical utility and samples aimed directly at the education of healthcare professionals and patient care, if they are "inexpensive" and do not offset routine business practices of the recipient. Such items include inexpensive software-applications (in particular smart phone apps) which support diagnostic analysis and therapy of patients, as long as they are related to products and indications of the member company.

The HWG foresees a limited number of exceptional rules, e.g. with regard to promotional gifts of minor value or to volume rebates in kind or money (see question 4.4). In 2018, a Higher Regional Court considered the limit for gifts of minor value for the benefit of healthcare professionals to be below EUR 1. However, this limit has not yet been confirmed by the Federal Supreme Court (*Bundesgerichtshof – BGH*) or reiterated in similar judgments of other Higher Regional Courts. Benefits may only be granted, offered or provided to healthcare professionals if they are relevant to the professional activity of the healthcare professional, e.g. they can be used for the physician's practice.

The question of whether or not the provision of gifts or other benefits is permissible, therefore, depends on the circumstances of the individual case taking into consideration the different regulations and rules and their exceptions.

### 4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

In principle, the above rules with respect to the offering and granting of gifts and other benefits to healthcare professionals also apply to medical institutions. Therefore, the pure funding of a nurse or the costs of a laboratory nurse by a company might also become critical with respect to a medical institution, provided that this is not part of a proper contractual relationship (with consideration).

It is, however, recognised that a company may grant donations to medical institutions if these donations are made:

a) to medical institutions which are recognised as non-profit organisations being able to issue donation certificates under the relevant tax law;

b) for the purpose of research and teaching, to improve health and patient care, or to realise advanced and further training for charitable purposes;

c) to official bank accounts held by the medical institution and supervised by its administration; and

d) dependent on the prior approval of the hospital administration.

In addition, it must be ensured that donations are made independently of sales transactions and are not intended to influence procurement decisions. Therefore, the potential involvement of hospital physicians in the solicitation of the donation has to be disclosed to and approved by the hospital administration.

The FSA-Code of Conduct Healthcare Professionals provides for additional rules with regard to donations: The documentation relating to a donation must be retained for at least five years. Furthermore, the member companies of the FSA must publish donations on an annual basis (pursuant to the FSA Transparency Code). In each case, donations may give rise to a suspicion that they might influence healthcare professionals in prescribing or applying specific medicinal products. Therefore, the rules against corruption in the German Criminal Code, which apply to employees in the public sector, as well as private, hospitals and – after the most recent reform – also to private practitioners and other healthcare professionals are to be observed and considered on a case-by-case basis.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

As a general rule, the Professional Code for Physicians in Germany prohibits the acceptance of any gifts or benefits by physicians that might influence their prescribing, therapeutic decisions, or which could be considered as a reward for such previous decisions.

Furthermore, German criminal law and the FSA-Code of Conduct Healthcare Professionals generally prohibit the provision and acceptance of any kind of benefits with respect to physicians that are granted in the context of their work, especially as consideration for carrying out purchasing or prescription decisions. Since the most recent reform, this applies to hospital physicians as well as to private practitioners and other healthcare professionals. As set forth above (see question 4.2), the FSA-Code of Conduct prohibits the promise, offer or granting of gifts to healthcare professionals. Only informational and educational materials or items of medical utility and samples may be provided.

However, it is permissible to provide educational services (e.g. scientific education or meetings) so long as the services are not intended to influence the prescribing or therapeutic decisions of the physicians, and provided that other conditions are satisfied as appropriate. For example, in some cases it will be necessary for a physician to obtain supervisory approval. In other cases, there may be additional regulatory limitations that must be satisfied, such as the FSA-Code of Conduct Healthcare Professionals as described above.

In addition, Section 128 of the German Social Insurance Code V (*SGB V*) – introduced in 2009 – must be observed in this context. Under Section 128 (2) SGB V, service providers, panel doctors and hospital doctors are prohibited from granting certain special benefits for care provided using medical aids and the further aforementioned products. This is intended to ensure that when prescribing medical aids and other products, doctors are not influenced in their decisions by their own financial interests and do not benefit from issuing a prescription or from directing insured patients to certain service providers. The act mentions the supply of devices or materials at no charge or at a discount, the performance of training measures and the making available of premises or staff or cost participation as examples of impermissible special benefits.

According to Section 128 (6) SGB V, the provision mentioned above (Section 128 (2) SGB V) also applies "between pharmaceutical companies, pharmacies, pharmaceutical wholesalers and other healthcare service providers on the one hand and towards panel doctors, hospital doctors and hospital operators on the other".

According to the Medical Association's professional code of conduct for physicians situated in Lower Saxony, companies are not allowed to provide any financial support (i.e. travel costs, accommodation costs and/or congress fees) to attend scientific congresses and other educational events to physicians situated in Lower Saxony. The Medical Association of Lower Saxony interprets this provision in a very strict way. However, this strict interpretation will not be applied in practice as long as the German Federal Chamber of Physicians (*Bundesärztekammer*) as the joint association of all State Chambers of Physicians (*Landesärztekammern*) has not defined its final position.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

In principle, the rules noted in question 4.2 above with respect to the offering and granting of gifts and other benefits to healthcare professionals apply. A volume-related discount is – as a general rule – considered to be a benefit within the meaning of Section 7 HWG, and therefore, is not permissible.

The exemptions to this general prohibition in Section 7 HWG allow a company to grant a volume-related discount in kind or in money only in the following cases:

a) Rebates in kind are prohibited for all kinds of pharmacy-only medicinal products (*apothekenpflichtige Arzneimittel*). This means that rebates in kind are only allowed for medical devices and medicinal products which may be sold outside pharmacies.

b) Rebates in money are prohibited if they are granted in violation of the Ordinance on Pharmaceutical Prices (*Arzneimittelpreisverordnung – AMPreisV*). This leads to the following rules:

- rebates in money between wholesalers and pharmacies are only permissible within the limits of the wholesale margin according to the AMPreisV;
- rebates in money for OTC products are permitted, since OTC products are excluded from the scope of AMPreisV;
- rebates in money to hospitals or hospital pharmacies are still permissible; and
- rebates in money between pharmaceutical companies and wholesalers/pharmacies: it is not absolutely clear whether this is permissible or not. The wording of the AMPreisV does not directly regulate these relationships. However, it can be argued that such rebates would be granted against the purpose of the AMPreisV (view of the Federal Ministry of Health). Accordingly, courts have interpreted the legislation in this way.

In 2017, the Federal Supreme Court delivered a judgment according to which rebates granted by a wholesaler which remain within the margins set forth in the AMPreisV are not prohibited. However, the question of whether and to which extent customary cash discounts (Skonti) are permissible, was not decided either in this judgment or in any other judgment of the Federal Supreme Court.

With regard to restrictions based on the AMPreisV, on 19 October 2016, the ECJ (Case C-148/15) has ruled that the German fixed price system for prescription-only medicinal products is incompatible with the principle of the free movement of goods under European law. The German legislator is still considering options on how to react to this ruling. For the time being, with regard to mail order pharmacies based in other Member States, the German pricing may no longer be applied.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Subject to the very few exceptions contained in Section 7 of the HWG, it is not permissible to grant, offer or provide healthcare professionals with any material benefits if these benefits are contingent on the purchase of medicinal products.

There are no explicit rules governing package deals, but rather the general rules outlined above apply accordingly. As the package deals could vary significantly as to their effect of inducement and influence on physicians, they have to be assessed on a case-by-case basis. Generally, with regard to Section 7 HWG, they constitute a rebate neither in kind nor volume as the package deal provides for one single price, covering both the medicinal products and the associated benefit. Accordingly, the jurisprudence considered a packaged deal consisting of the purchase of medicinal products and the purchase of an additional asset to an extraordinarily reduced price (here: garment bag) which has been linked to the purchase of medicinal products as prohibited under the general rules of UWG. Likewise, if the benefit granted to the physicians by providing the associated benefits is able to induce the prescription of the medicine, the package deal is prohibited subject to Sections 299a and 299b of the German Criminal Code. Depending on the market shares of the concerned pharmaceutical company, package deals may also be critical under competition law-related aspects.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

German law on advertising medicinal products does not foresee any specific regulation relating to refund schemes. However, there is a risk that the advertising for such a refund scheme might be considered as misleading advertising within the meaning of Section 3 of the HWG, and that a German court could classify such an advertisement as impermissible. A court might argue that such advertising may lead consumers to believe that the success of the product is guaranteed, as no pharmaceutical company would offer such a refund scheme if the company was not certain that the product's success was certain.

Different considerations might apply if the medicinal product is provided to the patient as part of the Social Health Insurance, e.g. if the medicinal product is remunerated by the German Social Health Insurance Funds and the refund scheme is contractually agreed between the pharmaceutical company and the Central Association of Health Insurance Funds (*Spitzenverband Bund der Krankenkassen*).

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

The HWG does not provide for any specific regulation concerning the sponsoring of continuing medical education (CME). Pharmaceutical companies may support CME through a reasonable financial contribution. The subject of the supported CME must stand in close relation to the application and/or research areas of the products, resp. of the pharmaceutical company. In return, image-promoting advertising activities in connection with the educational material shall or may be developed, e.g. by marking the educational material with the logo of the pharmaceutical company. Furthermore, such financial support may only be provided based on a written agreement with the publisher of such CME material.

The FSA-Code of Conduct Healthcare Professionals requires that the member companies of the FSA disclose such sponsorships. Section 128 SGB V prohibits special benefits (fees or other financial benefits) in connection with the prescription of medical aids, prescription-only drugs, medical products similar to drugs, dressing materials and enteral feeding. The performance of "training measures" is mentioned, among others, as an example of impermissible special benefits. However, it is not clear what exactly is meant by "training measures at no charge or at discount" and whether this term only refers to general ongoing training or also concerns true product training and familiarisations. In any event, the regulation is likely to be interpreted restrictively where training measures provided by the statute are concerned (for example, under the Medical Devices Act (*Medizinproduktegesetz – MPG*)). There also has to be a specific relationship of the special benefit to prescription practice.

For this reason, there are numerous indications that also general training events, relating to scientific, diagnostic and therapeutic aspects of products and their indications, etc. (that are normally offered by service providers at no charge or at a discount) will continue to be permissible if participation in these are not specifically linked to prescription decisions. This, however, is a prerequisite for the permissibility of such events under the Professional Code for Physicians in Germany (Section 32 MBO-Ä) and the applicable industry codes in any case. Please note that given the lack of any jurisprudence in this regard, the interpretation of this provision is likely to vary depending on the circumstances of individual cases.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Under German criminal law, there is a very broad and general prohibition against bribery *vis-à-vis* healthcare professionals employed by public institutions (Sections 331 to 334 Criminal Code), private hospitals and other treatment facilities (Section 299 Criminal Code) as well as with regard to healthcare professionals in private practice (Sections 299a and 299a Criminal Code) (see also question 4.3). The interactions between pharmaceutical companies and healthcare professionals or healthcare organisations are also

restricted due to recommendations and codes of conduct of the relevant trade associations (see question 1.1).

Since criminal liability of healthcare professionals has only recently moved into focus given the implementation of the anti-corruption law in the healthcare sector (*Gesetz zur Bekämpfung von Korruption im Gesundheitswesen*), one cannot yet fully assess what the future relationship among the relevant authorities will look like. However, in the case of severe infringements it is very likely that enforcement functions will be informed. Moreover, it is possible that competitors will contact enforcement functions to initiate an investigation in addition to seeking incentive relief regarding deviant behaviour.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The offering of hospitality to healthcare professionals is governed by various German legal provisions, e.g. the HWG, the SGB V (see also questions 4.4 and 4.8), the German Criminal Code and the Professional Rules for German Physicians, as well as the recommendations and codes of conduct of the relevant trade associations (see question 1.1), irrespective of whether the hospitality is offered in Germany or abroad.

According to these various rules, hospitality has to be reasonable and must not be offered to healthcare professionals or their associates to influence their prescribing and purchasing decisions or to renew products that have already been prescribed or purchased. Hospitality is only allowed as part of training and further educational events organised by a pharmaceutical company. Work-related meals are also permissible. However, a meal is not considered as being "work-related" if accompanying persons (e.g. the physicians' spouse) participate.

There are no explicit rules stating maximum amounts or limits relating to hospitality and meals. However, as a general rule which is based on guidance published by the German Federal Chamber of Physicians, hospitality must – generally – not exceed reasonable limits beyond the requirements of politeness and courtesy (generally EUR 50–60 per physician).

Just recently, and rather in contrast to this general approach of reasonableness, the State Chambers of Physicians of Bremen (*Ärztekammer Bremen*) has implemented changes to its ordinance on educational events (*Fortbildungsordnung*) to be effective as of 1 January 2018. These changes provide for concrete limits of amounts and preconditions to be met if physicians located in the Federal State of Bremen shall attend educational events and receive funding. For example, and amongst others, the amounts for meals are limited to the daily allowance granted under tax law, i.e. EUR 12 or 24. The reasonable amount for hospitality is defined as EUR 120 and is only justified if the educational event takes place for a duration of more than eight-and-a-half hours. Based on the wording of the amended ordinance, however, it is not clear whether the amount of EUR 120 has to be interpreted as a maximum amount for reasonable hospitality costs, thus an amount of EUR 125 being unreasonable, or whether the wording can be understood as setting forth the generally reasonable amount and exceptions thereto may be justified depending on the individual circumstances of each case. It remains to be seen how this ordinance will be applied in the future and whether any other State Chambers of Physicians (*Landesärztekammern*) will adopt this strict approach.

With respect to the applicability of various rules, pursuant to Section 20 para. 9 FSA-Code of Conduct Healthcare Professionals, hospitality offered to healthcare professionals on occasions such as international events is only governed by the limits stipulated in the local Code of Conduct which implements the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with Healthcare Professionals ("host country principle"). This means that the rules in the physician's country of origin are not taken into consideration.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The applicable legal provisions of the Professional Rules for German Physicians, as well as the relevant recommendations and codes of conduct, differentiate between "active" and "passive" participation in scientific meetings.

a) "Active" participation exists when the participant gives a presentation, moderates an event, or renders another reasonable service to, or on behalf of, the pharmaceutical company. A compensation for the active participation may only be paid on a contractual basis and may only be made if the active participation deals with products of the company or associated treatment forms. There must be a reasonable need for the active participation and the remuneration must be appropriate with regard to the services rendered (fair market value). In addition, hospital physicians are required to obtain the prior written approval of their superior/administration ("*Dienstherrengenehmigung*").

b) Physicians who are attending scientific meetings without giving a presentation or acting as speakers ("passive participants") may not be remunerated. It is, however, acknowledged that a pharmaceutical company may reimburse conference fees, and reasonable travel and accommodation costs. A pharmaceutical company should not bear additional costs. As with active participants, hospital physicians need the prior written approval of their superior/administration. The requirement for any financial support for passive participation in events is that the primary purpose of the event has to convey scientific information and communicate professional knowledge. Furthermore, an objective connection to the field of activity of the participating physicians must exist. Holding events in typical resort destinations or in particularly luxurious settings must be avoided since otherwise doubts could arise as to the professional relevance of the event. The organisation of tours or programmes for spouses or other accompanying persons is not permissible for the same reasons. Such conference travel support must, in each case, not be made dependent on any prescription or purchase decision.

The FSA-Code of Conduct Healthcare Professionals provides for additional rules as regards so-called international events. International events within the meaning of the FSA-Code of Conduct Healthcare Professionals are internal or external training events in a country in which the company organising, holding or supporting the event or supporting its participants is not domiciled.

Member companies of the FSA may only provide assistance for the participation in such international events, provided that: (i) the

majority of participants are not from the company's home country; or (ii) the relevant resources or expertise is available at the location of the event (e.g. recognised medical congresses with international lecturers). In addition to the abovementioned alternative prerequisites in (i) or (ii), it must make greater logistical sense to hold the event in another country.

The organisation, holding and/or sponsoring an international event are subject to both the German FSA-Code of Conduct Healthcare Professionals, as well as the applicable local code at the place of the event, interpreting the EFPIA-Code of Conduct (see question 1.1). The invitation and support of the participating physician in international events is subject to the German FSA-Code of Conduct Healthcare Professionals and the local code of the country in which the physician is active. In the event of a conflict of the applicable codes, the more restrictive code will apply. Furthermore, the member company of the FSA must notify any assistance in an international event in advance to its affiliated companies in the country where the event takes place.

Please note in this respect the recent change in the Medical Association's professional code of conduct for physicians situated in Lower Saxony. According to the amended code of conduct, companies are not allowed to provide any financial support (i.e. travel costs, accommodation costs and/or congress fees) to attend scientific congresses and other educational events to physicians situated in Lower-Saxony (see question 4.4).

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

In principle, the organiser of a scientific meeting is fully responsible for the content and the other elements of the meeting, such as hospitality granted to the participants. In the event a pharmaceutical company organises a scientific meeting with the help of an independent third party (e.g. an event organiser), the company remains responsible for the content and the hospitality.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Physicians can be paid for offering expert services to pharmaceutical or medical device companies. However, such payments may only be made under a contractual relationship between the physician and the company, e.g. a research and development or consulting agreement. In any case, such agreements may only be considered permissible if there is a real need for consulting services, which must be carefully examined and documented in each individual case. In addition, the decision to enter into an agreement with a specific physician must be justified by the physician's particular specialised expertise. The stipulated compensation must be reasonable with respect to the services to be rendered. Hospital physicians need the prior written approval of their superior/hospital administration. Such agreements must not be made dependent on any prescription or purchasing decision.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Physicians may be paid for participating in Post-Marketing Surveillance Studies ("PMS-Studies"). PMS-Studies may only be conducted if the pharmaceutical company has a legitimate and objective interest in obtaining the data and a written agreement has been concluded with the physician. In addition, the physician performing the PMS-Study must possess the appropriate professional skills and knowledge. Furthermore, a German court decided that PMS-Studies are only permissible provided that pharmaceutical companies perform such studies in strict compliance with the principle of non-intervention, i.e. that they must not make any study-specific guidelines with respect to the therapeutic decisions of the physicians.

The compensation for the involved physicians must be calculated in the style provided by the Fee Ordinance for Physicians (*Gebührenordnung für Ärzte – GOÄ*). As long as the documentation effort for the particular physician remains within a timeframe of 15 to 20 minutes, a lump sum (currently EUR 17.49 according to the normal compensation rate, number 80) shall be granted. A higher lump sum (currently EUR 29.14 according to the normal rate, number 85 GOÄ) may be granted if the documentation effort exceeds the "ordinary dimension" of the usual effort (i.e. a time exposure of more than 15–20 minutes). The aforementioned lump sums can be multiplied by up to 2.3 times of the compensation rate, depending on the degree of difficulty. Exceeding the rate by more than 2.3 times is generally only permitted if the particular documentation shows a special degree of difficulty or requires extraordinary time efforts. According to the GOÄ, typing fees are also billable at EUR 3.50 per commenced A4 page, as are postage and packaging expenses.

The FSA-Code of Conduct Healthcare Professionals provides additional rules for Non-Interventional Studies (NIS). Following the respective rules of the FSA-Code of Conduct, the planning, performance, analysis and quality assurance of NIS must be made within the responsibility of the head of the medical department of the member company. Apart from this, the FSA-Code of Conduct Healthcare Professionals recommends obtaining a positive opinion of the ethics committee. Furthermore, the FSA-Code of Conduct recommends obtaining a declaration of consent from the patient for the participation. Such information and consent shall be mandatory where this is required under data protection laws. The results of NIS need to be retained for 10 years and must be made available to those healthcare professionals involved in the study and to the general public (e.g. by the internet) 12 months after the finalisation of the study at the latest.

In this respect, it should be noted that a pharmaceutical company conducting an observational study must notify several authorities and institutions, including the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM*), without undue delay. If the physicians, in addition to the company's compensation, are reimbursed by the health insurance system, the notification shall include, amongst others, (i) the compensation paid by the pharmaceutical company, (ii) copies of the agreements with the physicians, and (iii) the reasons why the agreed compensation is appropriate.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Payments to doctors for their participation in market research or the development of product brochures are permissible provided that the

conditions outlined in question 5.4 (concerning the payments) and question 3.1 (concerning promotional material) above are met.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Apart from some restrictions, non-prescription medicinal products may be advertised to the general public. As a general rule, such advertisements relating to non-prescription products have to comply with the general provisions for advertising, i.e. they may not be misleading.

Furthermore, advertisements for medicinal products – whether for non-prescription or prescription-only products – have to provide certain basic information relating to the product (see question 3.1). The information must be set apart and clearly distinguished from the other promotional information and must be clearly legible. An advertisement for medicinal products in the print media or on television must be clearly separated and distinct from the editorial parts of these media. Advertisements that are directed to the general public must provide an invitation to seek the advice of a health professional and to read the packaging leaflet, as follows: "For risks and side effects read the package leaflet or ask your doctor or pharmacist."

However, advertising to the general public must not contain any advertising statements relating to (mostly severe) diseases explicitly mentioned in the HWG, including epidemics, tumour diseases, diseases of the metabolic system and internal secretion, diseases of the blood and blood-forming organs, and organic diseases. Furthermore, such advertisements to the general public must not contain expert opinions, statements that the product is recommended, tested or used by healthcare professionals, or certain pictorial representations.

It is important to note, however, that all restrictions on advertising of non-prescription medicines to the general public as laid down in the HWG have to be interpreted in light of Directive 2001/83/EC on the Community Code relating to medicinal products for human use. According to a judgment of the European Court of Justice (ECJ) of November 2007 (Case C-374/05 – "*Gintec*"), the Directive 2001/83/EC brought about complete harmonisation in the field of advertising of medicinal products and lists expressly the cases in which Member States are authorised to adopt provisions differing from the rules laid down by the Directive. Therefore, the restrictions contained in the HWG shall not be interpreted as being more restrictive than the restrictions in the EC-Directive. For example, the ECJ ruled that the prohibition on the use of statements from third parties (testimonials) – as laid down in the HWG – may not be interpreted as an absolute and unconditional prohibition as the use of third-party statements is limited under the Directive 2001/83/EC only by reason of their specific content or the type of person making the statement.

In addition, if an advertisement shall only serve as a reminder of the medicinal product (*Erinnerungswerbung*) it does not need to contain the basic information on the medicinal product mentioned above or the invitation to seek the advice of a health professional.

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No, prescription-only medicines may not be advertised to the general public.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

In accordance with the definition of advertising (see question 1.2), a disease awareness campaign, i.e. a campaign providing only factual information about a disease, but not mentioning the name of a specific product, would not be considered as being product advertising within the meaning of the HWG. Consequently, such campaigns would not be subject to the strict regulations of the HWG but, nevertheless, would need to be in compliance with the general rules of the UWG, i.e. they must not be misleading and comply with the rules relating to comparative advertising (see question 3.2 above).

However, such disease awareness campaigns might become critical in cases where only a specific medicinal product exists for the treatment of the underlying disease. In such cases, a court might argue that it is obvious for the end-consumer that only this specific medicinal product on the market can treat the disease and that this disease awareness campaign is therefore non-permissible as it circumvents the general prohibition on advertising for prescription-only medicines to the general public.

### 6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

There are no specific provisions in Germany which prohibit the issuing of information relating to medicinal products to the press. Therefore, pharmaceutical companies – as a general rule – are entitled to inform the press about the company and its marketing of authorised products by the means of press conferences, press releases or press portfolios. In each case, providing information to the readers should be the main purpose of such press releases and any advertising would only be considered as an unavoidable side effect of the publication. Furthermore, problems could arise if information given to the press is used to publish disguised advertising or editorially designed advertising (*Schleichwerbung*), which is prohibited by the HWG.

However, a pharmaceutical company should act carefully when providing information on prescription-only medicinal products to the press. Any information to the press about prescription-only products should contain only objective information relating to the product and any advertising effect of the press information should be avoided as advertising of prescription-only medicinal products is not permitted. Press releases referring to unauthorised medicinal products or unauthorised indications have to be considered cautiously. Although it is widely accepted that companies may inform the press about certain development milestones that have been reached, any promotional character in tone or in nature must be avoided (see also questions 2.1 and 2.3).

### 6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

The description of medicinal products and research initiatives in corporate brochures or Annual Reports must comply with the

aforementioned rules for advertising medicinal products to the general public (see questions 6.1 and 6.2). In general, such descriptions are permissible as far as they are necessary to provide the relevant information to, e.g., investors, current or future employees, etc., and are not misused to circumvent relevant advertising restrictions.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There are additional requirements set out in the FSA-Code of Conduct Patient Organisations. In collaboration with patient organisations, member companies have to stay neutral and respect the organisation's independence. Member companies are not allowed to establish own patient organisations. Moreover, the collaboration has to proceed in a transparent and open manner. The collaboration of member companies with patient organisations must not involve recommendations for individual prescription-only medicines or groups of medicines and the appearance of member company representatives at patient organisations must not be aimed at making promotional references to prescription-only medicines.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

In principle, Section 7 HWG does not allow the offering or supplying of gifts or other benefits to patients. However, exceptions may apply if the item is (i) of insignificant value and permanently and clearly visibly labelled with the name of the advertiser or of the advertised product, (ii) a trivia of insignificant value, or (iii) an accessory to the goods which is customary in the trade. Whether such exceptions apply has to be assessed on a case-by-case basis. It has to be noted, however, that courts tend to be very strict with regard to items of insignificant value. The limit is generally set below between EUR 0.5 and 1. If there is a medical rationale for providing an item to the patient, which is either necessary for the administration of the medicinal product or which supports the overall compliance of the patient, this may also qualify as an accessory to the goods which is customary in the trade. Although in this case the value thresholds do not apply, it has to be noted that the item's value has to be of subordinate importance compared to the medicinal product to which it is supposed to be an accessory. As regards the provisions of certain services to the patients, please see question 9.1.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

According to Section 42b of the German Drug Law, pharmaceutical entrepreneurs "shall place reports on all the results of confirmatory clinical trials substantiating the efficacy and safety of the medicinal product".

According to the legislator's reasoning during the legislative procedure, the purpose of the introduction of Section 42b is to give patients and doctors the possibility to receive further information on the characteristics as well as on the risks and the benefits of the drug. The report may be part of the decision-making process of whether or not to prescribe/whether or not to take the medicinal product. Furthermore, such reports shall support the scientific discussion.

The report must contain all of the results of the clinical trials and whether they are favourable or not. In addition, information regarding subsequent essential modifications to the trial protocol, as well as interruptions and early termination of the clinical trial, shall be included in the report. Furthermore, the findings of the report shall be drawn up according to the requirements of good clinical practice. With the exception of the name and address of the pharmaceutical entrepreneur or the sponsor, as well as the name and the address of the consenting investigators, the report may not contain personal or especially patient-related data. The report may be written in German or English. However, the disclosure of the report shall be without prejudice to the provisions protecting intellectual property and those protecting operating and trade secrets.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no legal requirement to disclose the transfer of values to healthcare professionals in Germany.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

In December 2013, the General Assembly of the FSA adopted the FSA Transparency Code approved by the Federal Cartel Office (*Bundeskartellamt*) on 8 May 2014. The FSA Transparency Code reflects the requirements of the EFPIA Disclosure Code.

The publication requirements set forth in the FSA Transparency Code relate exclusively to transfers of value in connection with research and development, donations (monetary or donations in kind) and other unilateral monetary or benefits in kind, training events and consultancy services. The rules apply to all member companies of the FSA (i.e. German companies and companies acting in Germany) regardless of whether any marketing authorisation has already been granted to the respective company.

For each individual recipient the disclosure must contain individual information, specifying the name of the recipient, regarding the totality of transfers of value granted during the reporting period to the extent such benefits fall under the respective categories.

However, the disclosure shall be made on an aggregated basis and without the individual recipients being named if such benefits fall under the category "Research and development".

The reporting period is the calendar year. The first reporting period was the calendar year 2015. Disclosure of the information shall take

place once a year and must take place no later than six months from the end of the reporting period.

The disclosure of the information shall be made on a publicly accessible website under the responsibility of the company. The information may also be published on a pan-European website of affiliated companies if the information relating to the member company of the FSA can be accessed there separately.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Transfers of value which can be allocated to one of the categories outlined above but for which a publication specifying the recipient's name is impossible for legal reasons, e.g. no consent from the recipient has been given to disclose such information, shall be published in aggregated form. The same applies if an individual only partly agrees to the disclosure of a transfer of value. In this case, in order to avoid a misrepresentation, the total value transferred to this individual shall only be disclosed in aggregated form.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

There are no particular provisions regarding the advertising of medicinal products on the internet. Therefore, the same rules as for other types of advertising apply.

Apart from the legal provisions relating to the healthcare sector, German websites have to comply with the relevant regulations of the German Telecommunication Services Act (*Teledienstegesetz*). This requires the display of specific information about the company responsible for the content of the site (i.e. name and address of the company, domicile, register number, etc.). In addition, the website must meet the general legal requirements (i.e. no infringement of copyright, no criminal content, etc.). Germany does not require a preview of a new website by any official supervisory body. Competitors may take direct action through the civil courts. They usually seek to obtain injunctive relief to stop advertisements violating their rights on the basis of the German Law against Unfair Competition. In addition, competitors may seek relief in substantive proceedings.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

There are no specific provisions in Germany regulating the level of security required with regard to the restriction of "healthcare professionals only" websites. However, a mere statement on a website where the details of prescription-only pharmaceuticals are only directed to healthcare professionals, or a simple unverified question asking whether the corresponding person is a health professional, is not sufficient. A company must instead establish a reasonable "safe access system" for accessing the pages directed to healthcare professionals only.

The safest and least complex solution is the installation of a password system, in which a service-rendering company such as DocCheck (www.doccheck.com) carries out the registration.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

As a matter of course, companies are completely liable for the content published on their websites. Therefore, content published on a company's website must not violate any law, e.g. German Criminal Code (*Strafgesetzbuch – StGB*), UWG, HWG, etc., or any third-party rights, e.g. intellectual property rights, personal rights, etc. In the case of a violation, the company is liable for omission, as well as for damages.

Additionally, companies may also be liable for content which is accessible via a link from the companies' website. In particular, companies are liable for linked content if such content appears from the user's point of view as the content of the company.

Moreover, companies may also be liable for content which is accessible via a link from the companies' website and which does not appear as its own content, but as third-party content. If the company is aware that the linked content violates any law or third-party rights, the company is obliged to remove the link. Otherwise, the company may be liable for such content. In addition, companies are also obliged to monitor and control, on a regular basis, the content of the sites that may be accessed by links. Such monitoring and control obligations exist prior to establishing the link, as well as after the link is established. The scope and frequency of the obligation depends on the circumstances of the individual case.

If, on the other hand, a third-party site links to the company's website, the company is generally not liable for the content of the linking site. However, even in such cases, the company might be liable for unlawful content of the linking website in cases where the company has knowledge of such content and has the ability to remove the link or to block visitors from following the link. The automatic blockage must be technically possible and economically reasonable.

Notwithstanding the above, it must be considered that a company may also be liable for third-party content which is published on the company's sites by third parties within forums or online portals. To that extent, the company is also obliged to remove illegal content after receiving notice. In addition, the company is obliged to monitor and review, on a regular basis, content which is published by third parties within forums, portals or other interactive parts of the sites. The scope and frequency of the monitoring obligations depend on the particular circumstances of the individual case, e.g. violations in the past, the company's financial power, etc.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

The general rules as mentioned in questions 6.1 and 6.2 also apply to information on websites.

Moreover, as with any company that maintains a website, pharmaceutical companies are also obliged to publish contact information on the website. Required contact information includes the name of the company, domicile, address, legal form, representatives, an email address which enables the user to contact the company quickly and easily, commercial register, registration number of the commercial register, competent regulatory authority, sales tax identification number, etc. Such contact information must

be legible and easily obtainable for each user of the website when browsing on any page of the site. Usually such information is called the "imprint" or "contact" and can be accessed via a link on the page's bottom line or navigation bar.

If editorial content is published on the website, special press-related obligations are applicable, e.g. the name of a person responsible for the editorial content must be made available on the website.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

No, there are no specific rules, laws or guidance controlling the use of social media by companies. In fact, the same general principles as set forth above apply.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The health policy environment and the playing field for the development, sale and reimbursement of medicinal products are in a state of upheaval. They increasingly require the involvement of widely diverse institutions in the healthcare system. This simultaneously results in new and/or more tightly-knit collaborative relationships between pharmaceutical companies and these institutions, including their employees.

With regard to the relationship between the pharmaceutical industry and physicians, the reform of the German Criminal Law to combat corruption in the healthcare sector (which entered into force in June 2016) can still be considered as a key development. As explained above in further detail, it extended criminal liability for corruptive practices to private practitioners. This change in the law has incited many companies to reassess all advertising activities relating to the provision of benefits to healthcare professionals. However, in anticipation of the legal developments, many companies have already treated self-employed physicians in the same way as (privately or publicly) employed clinic physicians. This is also the approach followed by the FSA-Code of Conduct Healthcare Professionals.

Nevertheless, in some cases, this has led to important developments in the market and widely used advertising practices have either almost completely disappeared (e.g. the provision of free-of-charge testing devices to physicians which are ultimately handed over to the patient), or have been limited as to their extent and scope, taking into account the new anti-corruption laws. New tech instruments, e.g. medical apps (to be used by patients or physicians), have increasingly moved into focus as pharmaceutical companies may want to provide them to patients and/or physicians as an "add-on" to facilitate the therapy performance and/or increase therapy outcomes. The permissibility of such supply is particularly dependent on the circumstances of the individual case, especially the functionality and purpose of the medical app.

Further developments relate, for example, to the provision of so-called patient support programmes which aim to support patients with the administration of a prescribed pharmaceutical that follow a complex therapy regime. The service usually includes private nurses visiting the patients at home, providing assistance with the therapy in order to support and safeguard the success of the therapy. The permissibility of these patient support programmes has been thoroughly assessed and reconsidered by the FSA which led to an amendment to the guidelines to the FSA-Code of Conduct Healthcare Professionals (*Leitlinien des Vorstands des FSA*) according to which, amongst other requirements, such measures ensuring the correct application and use of the pharmaceutical (*gebrauchssichernde Maßnahmen*) must follow a medical rationale to be assessed and determined by the medical department of the company.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

As major reforms of the Law on Advertising in the Field of Healthcare (*Heilmittelwerbegesetz – HWG*) and of the German Criminal Code have been implemented over the past few years, additional changes are not expected in the next year.

However, the provision of unilateral benefits (such as conference travel support to healthcare professionals) remains under discussion. In this regard, the State Chambers of Physicians of Lower Saxony has expressed the view that costs in connection with the passive participation of doctors in Lower Saxony in continued training events give rise to the impression that the independence of medical decisions is being influenced thereby. As a consequence, a political discussion about conference travel support has been initiated and is still ongoing at a federal level within the German Federal Chamber of Physicians (*Bundesärztekammer*). In this regard, it has to be noted that the MedTech Europe Code of Ethical Business Practice contains a prohibition against the provision of direct conference support to participants who do not have a *bona fide* professional interest in the information being shared at the conference.

With regard to rebates granted by mail order pharmacies established in other Member States and which are in contradiction with the German pricing rules set out in the AMPreisV, a political discussion is still ongoing on how to implement the ECJ ruling described above (see question 4.5). The German legislator has different options to react to this judgment: (i) without significantly changing the legal framework, mail order pharmacies established in other Member States could be exempted from the German pricing rules; or (ii) the judgment may also set in motion a more radical change of the legal framework resulting in either a ban on the sale of Rx products by mail order or the abolition of the current German pricing rules in order to avoid disadvantages for German dispensing pharmacies. Until today, almost two years after the EJC ruling, the German legislator has not yet decided how to react on the judgment. Although the current coalition agreement (2018) indicated that a ban on the sale of Rx products by mail order is the most likely pathway to be followed, a respective draft bill implementing such ban has not yet been presented and discussions are still ongoing. Just recently, due to the absence of any measures taken by Germany, the European Commission decided to send a reasoned opinion, urging Germany to comply with the EU rules on the free movement of goods. Otherwise, the Commission may decide to refer Germany to the Court of Justice of the EU.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Whereas the past few years have shown significant improvement in the area of internal standard operating policies regulating in detail all kinds of promotional activities and interactions with healthcare professionals, the competent authorities and the relevant courts are

increasingly focusing on another compliance-related aspect. This concerns the organisational structure of pharmaceutical (and other) companies in relation to a proper delegation and ongoing supervision and control by board members. It has become evident that many companies have certain deficiencies as to the legal validity of the allocation and delegation of such duties and responsibilities. Furthermore, enforcement authorities often demand documentary proof, which companies are unable to provide in the requested format.

In the context of the new anti-corruption law in the healthcare sector (*Gesetz zur Bekämpfung von Korruption im Gesundheitswesen*), it could be noted that competent enforcement functions use these provisions continuously to further examine certain forms of cooperation. This, in particular, applies to the collaboration between physicians, between physicians and hospitals and their activities related to the assignment of patients among each other. In particular, the focus has been on hospitals and their management of assigning patients after the in-patient treatment for the following treatment by local practitioners.

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# Greece

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products in Greece is governed and regulated by a series of legal texts, which separately demonstrate specific provisions with regard to the advertising of medicinal products. More specifically, the following laws and regulations in force at this time are applicable: 1) Legislative Decree 96/1973 on the trading of pharmaceutical and cosmetic products; 2) Law no 1316/1983 on the establishment, organisation and competence of the National Organization for Medicines (EOF), the National Pharmaceutical Industry, the State Pharmaceutical Warehouse and other provisions; 3) Ministerial Decision (MD) no Y6a/22261/2002 on the advertising of medicinal products that may be administered without medical prescription; 4) MD no DYC3a/32221/2013 on the implementation of Directive EC 2001/83 of the European Parliament and of the European Council on the Community Code relating to medicinal products for human use; 5) MD G5a/59676/2016 on the transposition of Regulation 536/2014 on clinical trials; 6) Physicians' Ethical Code; 7) Pharmacists' Ethical Code (6) EOF's circular no 44787/12-5-2017 in regards to the advertising of medicinal products as amended by EOF's circular no 16251/13.2.2019); and 8) the Hellenic Associations for Pharmaceutical Companies' (SFEE) Code of Ethics on the promotion of prescription-only medicines, which also foresees for its members respective provisions with regard to the advertising and promotion of medicines. The provisions of the SFEE are binding for its members only; however, many local pharmaceutical companies voluntarily comply with its provisions, which ensure compliance at a maximum level with all applicable legislation in the pharmaceutical field.

### 1.2 How is "advertising" defined?

According to article 118 MD no DYC3a/32221/2013, advertising of medicinal products means any form of door-to-door information, customer engagement or incentives designed to promote the prescription, procurement, sale or consumption of medicinal products. It includes in particular: the advertising of medicinal products to the general public; the advertising of medicinal products to persons authorised to prescribe or supply medicinal products; medical visitors to persons authorised to prescribe; the supply of samples; encouraging the supply of medicines or prescribing them by offering or promising benefits or gifts, whether in cash or in kind, unless their value is minor; the sponsorship of marketing meetings attended by persons authorised to dispense or prescribe prescriptions; the sponsorship of scientific conferences involving persons authorised to prescribe or supply medicinal products; and in particular, the travel and subsistence expenses of the participants.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

In practice, pharmaceutical companies are required to have a scientific service/committee responsible for providing information on the medicinal products they market. The function of this service is to reply to all queries from patients/consumers, healthcare professionals (HCPs) (physicians, pharmacists, etc.), medical sales representatives or other sources (e.g. government agencies, scientific institutions, regulatory authorities). The scientific service must ensure compliance at all times with the existing legislation regulating the advertising and promotion of medicinal products to the public as well as HCPs. Hence, all personnel must receive adequate training with regard to the applicable rules governing promotion and advertising in order to verify that all promotional materials are in compliance with the existing legal framework, properly inform the public as well as HCPs with regard to the product's characteristics and finally, perform all internal procedures necessary to achieve full compliance with local laws as well as guidelines.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no binding requirements with regard to the obligatory adoption of SOPs governing advertising activities or to employ personnel with a specific role. However, given the operation of the scientific service that all pharmaceutical companies should hold and aim to ensure each company's compliance, most pharmaceutical companies usually adopt internal procedures in the form of SOPs in order to document the advised internal procedure to be followed by all employees, in accordance with the applicable rules regarding the advertising and promotion of medicinal products. In accordance with the SFEE's Code of Ethics (article 11), it is advised that the

scientific service in charge of certifying the printed material is integrated into the medical affairs department of the pharmaceutical companies, depending on the organisational structure of each company. The scientific service should preferably include a medical doctor or a pharmacist or other properly qualified HCP who will be responsible for approving all promotional material before its release. Such person must certify that he/she has examined the final form of the promotional material and has found it to comply with the requirements of the law and the Code. The person in question cannot be a member of and/or report to the scientific service and promotion department, and no conflict of interests must exist.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

According to MD no 32221/2013, each pharmaceutical company should give to the National Organization for Medicines (EOF), a copy of any advertising made by her, accompanied by a form indicating the transmission, the mode of transmission, registration or circulation and the date of first transmission, registration or circulation. Following this, the above MD states that the pharmaceutical company (MAH) must also ensure that the advertising of medicinal products carried out by her complies with the provisions of the existing legislation, and also that her medical representatives are adequately trained and comply with their obligations under article 125 (2) and (3) of the MD. Moreover, according to the EOF's circular no 44787/12.5.2017, which repeats the above explained provisions along with the form filed by each pharma company, the latter must also file the product's Summary of Product Characteristics (SmPC). The above notification of each advertisement to be transmitted by each pharma company is not submitted for approval, however, it is required for the purpose of *ex post* audits on behalf of the EOF. However, the EOF explicitly clarifies that the above provisions do not apply to vaccine campaigns which are subject to authorisation and must be submitted at least 60 days in advance before the EOF.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The EOF is primarily responsible for supervising compliance with the existing legislation with regard to the advertising of medicinal products, and may intervene whenever they detect any breach of the above-mentioned provisions. In particular, in accordance with article 129 of the MD, the EOF ensures that there are adequate and effective means of controlling the advertising of medicines in the Greek territory. Hence, the EOF may intervene whenever it believes that measures are required to be taken, especially in the protection of the public interest. For example, the EOF may directly prohibit misleading advertising, either for preventive or repressive purposes, even if no actual loss, damage, intention or negligence on behalf of the advertiser is proved. Moreover, in order to eliminate the long-term effects of misleading advertising which has been banned, the responsible court may order the full or partial publication of that decision in the form it deems appropriate and, in addition, the publication of a corrective announcement on behalf of the company. Finally, self-auditing organisations such as the SFEE and SEE also reserve the right to perform audits regarding compliance with the existing legislation, and may impose various sanctions and fines. Respectively, anyone with a lawful interest may also bring a civil or criminal action before the competent courts against any company publishing an unlawful and offensive advertisement.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

As previously stated, the EOF is the authority for supervising and accordingly regulating the advertising of medicinal products. Hence, when identifying a breach of the existing legal rules, the EOF may impose a fine of up to 22,000 euros, and if the breach has been repeated, a fine of up to 44,000 euros (articles 131 and 175 par. 2 of the MD). Accordingly, the EOF may also order the publication of corrective statements.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

Competent authorities and self-regulatory bodies, such as the EOF, operate separately and completely independently when supervising compliance with the existing framework regarding the advertising of medicinal products. Hence, each one of them may perform its own inspections and impose different fines. In practice, it has been observed that even though the above bodies act separately, in case of an adverse finding, it is usual for the responsible authority (EOF) to also proceed with an investigation, following the information provided.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The existing law does not foresee specific actions to be taken on the basis of unfair competition. However, in accordance with the existing legislation governing unfair competition, any company that has a legitimate interest and rightful claim may bring an action before the competent court, seeking interim measure, indemnification or any other rightful claim.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

In accordance with the EOF's circular no 44787/12.5.2017 as amended, medicines that have not been approved in Greece or have been submitted for approval to the EOF or EMA and are in the process of evaluation, cannot be advertised in the medical press or promoted in scientific events. However, the presentation of new scientific data in scientific events is allowed, provided that the information disclosed does not make reference to any commercial name while it must also be explicitly noted that the active substance has not yet been approved. Finally, approved medicines that have not yet received a price may be promoted with reference to an indicative value. According to the SFEE's Code of Ethics, the use of unpublished data regarding the efficacy and safety of products (data on file) for promotional purposes is prohibited. Such data may constitute the subject matter of discussions between HCPs and the scientific service of the pharmaceutical company, but cannot be included in promotional material. Only general data are acceptable, such as the total number of patients in clinical programmes where the medicinal product has been studied and the total duration of the clinical programme and financial data, i.e. data that only the company possesses and can provide upon request.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

As already explained in question 2.1, the publication of information on unauthorised medicines and/or off-label information is strictly forbidden by the existing legislation. Only by exemption is the presentation of new scientific data information to HCPs on new medicines allowed, and must be in the context of a scientific event.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

The advertisement of medicinal products which have not yet been authorised as well as off-label information to the general public and HCPs, is strictly forbidden according to the existing legislation. Hence, companies are not allowed to issue press releases on unauthorised medicines and/or off-label information with the exemption of press releases with information regarding new and important scientific information provided that no reference is made with regard to the respective product's commercial name.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

As already explained, such information cannot be sent to HCPs on a promotional basis, given the law's strict ban. However, informational briefing with regard to new scientific information regarding an active substance may be disclosed, provided no reference is made with regard to the respective product's commercial name.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The ECJ judgment in the *Ludwigs* case has not been respectively implemented in the existing legal and regulatory framework. However, a patient's physician may prescribe a non-approved medicinal product and such may be imported in Greece, provided that such request has been granted by the respective regulatory authorities (the Institute of Pharmaceutical Research & Technology).

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

The existing legal framework does not specifically regulate this matter. However, given that in general the advertising and promotion of unauthorised medicines is strictly prohibited, it is advised that such information on unauthorised medicines not be sent to institutions.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The existing legal framework does not specifically regulate this matter. However, HCPs may be involved in market research exercises concerning unauthorised medicinal products, provided that such involvement does not imply any indirect advertising or promotion which is strictly prohibited for such products.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Each advertisement shall contain the following:

a. essential information consistent with the summary of product characteristics (SmPC);

b. the supply classification of the medicinal product (i.e. prescription-only or non-prescription);

c. the Yellow Card, as required by the EOF;

d. the selling price or indicative price of the various presentations; and

e. the reimbursement rate by social security funds may also be included. It must also be noted that medical information with respect to a medicinal product addressed to persons authorised to prescribe or supply medicinal products may include only the name of the medicinal product, or the international non-proprietary name – if applicable – or the trademark, in case the communication is exclusively intended as a reminder.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

MD no 32221/29.4.2013 sets out the provisions regarding the advertisement of medicinal products to the general public and also to HCPs, in articles 121 *et seq*. Advertisement of medicinal products to HCPs may contain a scientific study that is not stated in the SmPC, under the requirement that all data and quotations are faithfully reproduced, mention the precise source from which they were taken and reflect the current state of scientific and technological affairs.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

According to article 122 par. 1f, an advertisement addressed to the public is prohibited when it refers to the opinion of scientists, HCPs, or other famous people who, although not scientists or health professionals, can, due to their fame, promote the consumption of medicines.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There is no specific requirement for this, but it must be noted that comparisons must be correct, accurate, objective and unambiguous and must be based on relevant and comparable aspects of the medicinal products, as well as on an up-to-date evaluation of all the evidence, reflecting that evidence clearly. They must not be directly or indirectly misleading, they must not distort the scientific facts and must be capable of scientific substantiation along with comparisons and/or statistical data, and the following must always be stated: i) the statistical significance level (P/P value or confidence intervals) must be stated for data that are statistically non-significant; and ii) further statistical data analysis, when such data have not been published (i.e. extrapolation of results by the company), is not allowed. Where the clinical significance is not known, this must be stated on the same page. All factors under comparison must be stated, accompanied by clarifications where and as necessary.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Trade names of products of other pharmaceutical companies must not be used without the prior consent of the marketing authorisation holder of the respective medicinal product (article 6.10 SFEE's Code of Ethics). A comparative advertisement is only allowed if it is not misleading, compares only similar products as regards their nature and indications, compares objectively one or more essential characteristics of the product, does not in any way diminish the value of the product, trademark or brand name of the competitor, does not profit illicitly from the fame of the competitor's trademark or brand name, does not generate any confusion among the products or entities that are being compared and must be capable of scientific substantiation.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The content of scientific papers and/or proceedings of congresses to healthcare professionals should be strictly scientific and educational, and their distribution should have, as a purpose, the promotion of specific medicines and their respective prescription.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Such ban is not stated in Greek legislation. However, it must be noted that such an advertisement would not include the minimum requirements set out by the Ministerial Decision as described above. Therefore, teaser advertisements are not permitted.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

In accordance with the existing legislation, the MAH of Product A may promote the combination use as such has already been approved for a specific indication according to the Product's SmPC. However, provided that Product's B approved SmPC has not been authorised for such indication, the combination use should not be promoted by the MAH of Product B, given that the promotion of medicinal products for off-label indications is strictly forbidden according to the existing legislation.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

The production, import and free distribution of medical samples, irrespective of packaging, to physicians and dentists for information purposes, is permitted only pursuant to special permission from the EOF in accordance with the provisions in force. The permission, granted in exceptional cases, determines the packaging, the overall quantity, the time and mode of distribution and any other information as necessary.

Pharmaceutical companies must also have suitable control and calculation systems for the samples they distribute and for all medicinal products they handle through their representatives. Furthermore, a sample cannot be larger than the smallest presentation of the medicinal product on the market and all samples must be marked "free medical sample – not for resale", or words to that effect, and must be accompanied by a copy of the summary of product characteristics (SmPC).

The provision of samples distribution is not permitted for the following medicinal products: (a) medicinal products containing substances which are defined as psychotropic or narcotic by international conventions, such as the 1961 and 1971 United Nations Conventions; and (b) any other medicinal product for which the provision of samples is considered inappropriate by the competent authorities.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

According to article 14 of the SFEE's Code of Ethics, it is permitted to offer a medical/educational devices/applications item of insignificant value, of up to 15 euros (per item) with VAT included, that is closely associated with a daily HCP practice, such as:

i. applications for mobile phones/computers which, due to their nature, are not characterised as medical technology products (e.g. they do not serve diagnostic or dosing purposes, etc.);

ii. anatomy and/or physiology models (physical or electronic, e.g. CD/DVD/locked USB);

iii. anatomy maps (physical or electronic, e.g. CD/DVD/locked USB);

iv. educational material for patients via the HCP in the form of supporting material, e.g. nutrition/exercise advice, or in the context of a disease awareness campaign approved by the competent authorities;

v. printed or digital publications including guidelines from Scientific Societies – provided they do not describe outside the approved indications and dosage; or

vi. printed or digital publications of therapeutic protocols.

All the above materials must be notified to the EOF. Any other donation, sponsorship or benefit in kind to HCPs is prohibited.

In the same context, article 126 of MD no 32221/29.4.2013 describes that pharmaceutical companies are not allowed to provide HCPs with gifts or benefits of any kind, unless they are inexpensive and relevant to the practice of medicine or pharmacy.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Donations, grants and benefits in kind to foundations, institutions, organisations or associations that are comprised of HCPs as well as hospitals are only allowed if: i) they are made for the purpose of supporting healthcare, research, training; ii) they are documented and kept on record by the company; and iii) they do not constitute an inducement to prescribe, sell or purchase specific medicinal products. Donations, where allowed, may be in kind or in money. Pharmaceutical companies are required, on an annual basis, to disclose information about their donations, sponsorships, or benefits in kind on the SFEE's website. Such donations may not exceed 1% of the total annual turnover of a pharmaceutical company.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Pharmaceutical companies should not, in any case, provide any medical or educational goods and services or benefits of any kind either directly or indirectly that could lead to changes in prescribing patterns, as such practice is considered strictly unlawful.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Discounts to institutions purchasing medicinal products are not regulated by the existing legal framework on advertising, as such arrangements do not fall within the meaning of advertising in accordance with the legislation currently in force. Such arrangements are indeed permitted provided that the conditions set out by the applicable Ministerial Decisions governing the pricing of pharmaceutical products are met (currently Ministerial no 28408/2016). Additionally, the offering of discounts and profit margins should be limited and carefully planned by pharmaceutical companies in accordance with the provisions of the applicable competition and public procurement legislation.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

As already explained, the offering of any additional benefits linked to the purchase of medical products is not considered legitimate, since it may strictly aim to promote such products. Respectively, commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits is also not encouraged, unless the apparatus, for instance, is considered as an integral and necessary part of a medicine (i.e. apparatus for the application of the medicine). In addition, patient support programmes sponsored by pharmaceutical companies – which are aimed at informing patients of their disease and medicine application – are allowed, in accordance with the SFEE's Code of Ethics and the existing data protection laws, including the GDPR.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

The possibility of a refunding scheme is not specifically regulated by Greek law. In cases of adverse events, pharmacovigilance procedures are always enacted by pharmaceutical companies, however, in such cases, a refund scheme is not advised given that

such action could imply a guarantee with regard to the medicine's efficacy, or with regard to the arising of zero adverse effects, which contradicts the existing legal framework on the advertising of medicinal products.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

In accordance with the EOF's circular no 27810/2018 on the organisation of scientific events, pharmaceutical companies may sponsor continuing medical education through scientific events or by granting scholarships and educational grants to non-profitable organisations. In accordance with the SFEE's Code of Ethics, sponsorships, grants and donations should be requested by the respective organisations and should always be documented in writing. Furthermore, such grants should be disclosed on each pharmaceutical company's website, in accordance with the provisions of Law no 4316/2014.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Anti-bribery rules are adopted vigorously in order to transparently regulate interactions between HCPs and HCOs. It is common practice that most pharmaceutical companies include extensive anti-bribery clauses in their written agreements with the HCPs and HCOs. At the same time, all public authorities, such as the EOF, the Public Prosecutor and other auditing authorities along with the General Secretariat for the Battle of Corruption collaborate with each other in order to prevent corruption practices and promote transparent relationships and interactions between pharmaceutical companies and HCPs and HCOs.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

According to the most recent circular issued by the EOF with protocol no 27810/2018, any company falling under the scope of the EOF may cover the accommodation costs of a HCP participating in a scientific event, under the circumstance that he has properly acquired beforehand a sabbatical leave from his employer. These costs may not exceed the amount of 70 euros daily for meals including VAT and 150 euros for accommodation including VAT. If the scientific event takes place abroad, the daily cost for meals may not exceed the amount of 150 euros including VAT for meals and the amount of 400 euros including VAT for accommodation, as per the EOF's 25.5.2018 announcement.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

A healthcare professional may not be remunerated for attending a scientific meeting, as already stated above in question 5.1. According to the EOF's circular no 27810/2018, only travelling, registration and accommodation costs may be covered.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

A pharmaceutical company sponsoring or organising a scientific event is also responsible for the content and arrangements of the event, i.e. obtaining the EOF's prior approval. If a pharmaceutical company sponsors a HCP to attend a scientific event, it must electronically submit all the information two months before the event, which is included in the EOF's circular no 27810/2018.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

HCPs may participate in advisory boards and provide consulting services to pharmaceutical companies, with the receipt of an honoraria payment. In particular, article of Law no 36 4272/2014 as well as the EOF's respective circular no 27810/2018 sets out the conditions in order to participate in advisory boards. It is worth noting that physicians employed in NHS hospitals and Health Centres are required to obtain permission from the hospital or Health Centre in order to participate in such events. For HCPs participating in advisory boards held abroad, the following is required: a) an invitation from the organiser to the experts; b) cover of the expenses by the scientific entity or the pharmaceutical company registered abroad; and c) submission of the document with the description of his scientific work and justification of his expertise to the specific subject matter of the advisory board. Moreover, the provision and payment of consulting services to pharmaceutical companies is allowed, however, HCPs employed in NHS hospitals are prohibited from offering their services with the above-mentioned exemptions (advisory boards, scientific events).

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

HCPs may participate in post-marketing surveillance studies provided that such are conducted in accordance with MD DYG/89292/2003, and have the approval of the National Ethics Committee. In particular, HCPs may be remunerated for their participation in such studies. Provided that such studies are

conducted in NHS hospitals or University clinics, the HCPs' payments shall be deposited to the entities foreseen by the legislation in force (Special Research and Development Accounts ELKE and ELKEA) which shall transfer it to the beneficiary after the appropriate deductions.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

In practice, HCPs may participate in market research involving promotional materials and may be paid in accordance with the foreseen fair market value. However, HCPs employed in NHS hospitals are strictly prohibited from offering their services as explained above. Furthermore, it must be noted that the participation and payment of HCPs in such activities is not concealing any inducement to prescribe, sell or purchase specific medicinal products.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

According to the MD (32221/2013) the advertisement of non-prescription medicinal products is allowed, provided that a series of conditions are fulfilled. In particular, according to articles 119 and 121, all advertising to the general public of a medicinal product must be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product. Moreover, it must include the following minimum information: a) the name of the medicinal product, as well as the common name, if the medicinal product contains only one active substance; and b) the information necessary for the correct use of the medicinal product, which includes an express, legible invitation to carefully read the instructions on the package leaflet or on the outer packaging, as the case may be. Furthermore, the advertising of a medicinal product to the general public must not contain any material which: (a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail; (b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product; (c) suggests that the health of the subject can be enhanced by taking the medicine; (d) suggests that the health of the subject could be affected by not taking the medicine; (e) is directed exclusively or principally at children; (f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products; (g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product; (h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural; (i) could, by a description or detailed representation of a case history, lead to an erroneous self-diagnosis; and (j) refers, in improper, alarming or misleading terms, to claims of recovery; uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

The advertisement of prescription-only medicines is strictly forbidden according to article 120 of the Ministerial Decision.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

In accordance with the EOF's respective circular on advertising, information regarding human health or diseases is not considered an advertisement provided that no direct or indirect reference to specific medicines is being made. Hence, disease awareness campaigns containing strictly educational information are indeed permitted as long as they do not make any direct or indirect reference to a specific medicine.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

As already explained, advertising of prescription-only medicines to the general public is strictly prohibited. Therefore, the issuance of press releases regarding prescription-only medicines to non-scientific journals is in general prohibited, unless the information included is strictly informative and does not make any direct or indirect reference to a specific medicine. Furthermore, the reference on developments in relation to unauthorised medicines or unauthorised indications is not permitted according to the provision of the MD as well as the SFEE's Code of Ethics (article 3).

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

The scientific service of each pharmaceutical company is competent to ensure the latter's compliance with regard to the applicable legislation on the advertising and promotion of medicines. Hence, the description of products in corporate brochures and annual reports should not include any hidden intention to directly or indirectly advertise or promote the pertinent products.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Pharmaceutical companies are allowed to grant donations, grants and benefits in kind to foundations, institutions and organisations (including patient organisations) or associations. Such benefits should be granted in order to support the patients' needs and interests and not promote nor advertise the company's products. According to the SFEE's Code of Conduct on the relationship between pharmaceutical companies and patient organisations, any financial support provided by pharmaceutical companies to patient organisations must be covered by a written agreement (article 2). The agreement must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc.) while it must also include a description of significant indirect supports (e.g. the donation of the public relations agency's time and the nature of its involvement) and significant non-financial support.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The provision of items to patients is currently not regulated by the existing legislation. As explained above, benefits towards patients can be granted via patients' organisations with the fulfilment of the conditions set out here above. Furthermore, pharmaceutical companies may run patient support programmes, through which patients are educated and supported with regard to their disease.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Article 66 par. 7 of Law no 4316/2014 specifically states that expenses made with regard to research and development activities, as well as non-interventional studies and clinical trials will be disclosed in aggregate from every pharmaceutical company.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

According to article 66 of Law no 4316/2014, every pharmaceutical company must disclose by name, on its website and at the designated site of the EOF, within six months from the end of each calendar year, all benefits granted to HCPs and HCOs including but not limited to donations, sponsorships, registration fees for participating in conferences and scientific events of the medical community, as these are specifically defined in the relevant circulars issued by the EOF, travel and accommodation costs as well as any other benefit based on an agreement or at its free will, regarding the promotion of the prescribed medicinal products. It is also worth noting that the Hellenic Data Protection Authority issued two opinions in 2016 and 2017, respectively, which concluded that Law no 4316/2014 refers only to promotional conferences, excluding thus from its scope any ToVs towards HCPs related to purely scientific events.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The European Federation of Pharmaceutical Industries and Associations (EFPIA), adopted the "EFPIA Disclosure Code", which all Member States, including Greece, have transposed into their national codes. As a member of the EFPIA, and in line with these initiatives at the European level, the SFEE adopted its own Disclosure Code, which requires all SFEE member companies to disclose details on their transfers of value to Healthcare Professionals (HCPs) or Healthcare Organisations (HCOs) (name of HCP/HCO, type and amount of transfer – e.g. participation in conferences, fees for consultancy and other services, etc.). This information will be disclosed through a dedicated platform on the SFEE website, which will gather data from all member companies and will be freely accessible by the public. Every company which is a member of the SFEE is obliged to follow the guidelines set out in the Disclosure Code when they disclose their transfers of value to healthcare professionals and healthcare organisations.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

The obligation to disclose such transfers derives directly from the provisions of Law no 4316/2014; therefore, one does not have the option to disagree with such a transfer. According to article 66 par. 7b of Law no 4316/2014, failure to provide such information may lead to fines ranging from 30,000 to 100,000 euros.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

There are no specific legal requirements regulating Internet advertising. The general rules regarding the advertising of medicinal products towards the general public and HCPs are respectively applied to all advertising actions taking place through the Internet.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

According to article 27.3.3 of the SFEE's Code of Ethics, measures must be adopted in order to ensure that only those professionally dealing with heath issues will have personal access via a user name and a password. Hence, a username and strong password ensure that access to the site's content is strictly limited to HCPs.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Access to the content of an independent website via reverse linking should be treated cautiously and with specific attention to any copyrights as well as the Terms of Use of the relevant website. In practice, for such cases it is advised to firstly obtain the consent of the independent website's owner and to also include a disclaimer in the company's sponsored website Terms of Use, stating that the company disclaims any liability with regard to the accuracy or lawfulness of the content of the linked website.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

In accordance with the SFEE's Code of Ethics (article 27.3) a pharmaceutical company's main corporate website can include her/his profile, history and news on its social activity, as well as a list of products with their respective approved package leaflet. The company's site may also include texts informing the public on prevention and health issues, but it must not connect them with the respective medicinal products that might be offered and/or their package leaflets. The material included must be primarily approved according to the internal procedures of the company. The same applies for any change or addition to the website. With regard to pharmaceutical company websites including exclusively informative texts on prevention and health issues, it is noted that their texts and pictures, as well as any material revision thereof, should not include any direct or indirect promotion of medicinal products. Therefore, no references should be made with regard to trade names and/or names of active substances of medicinal products, nor any references to therapeutic options connected to general pharmacological groups. Moreover, texts and information should be quoted in a neutral and objective manner with precise reference sources while a phrase to the following effect should be added: "This is intended for general information purposes and is no substitute for advice from a physician or another competent HCP." The sources of the information included should be kept on record by each pharmaceutical company and be made available to the EOF upon request. For reasons of transparency and responsibility, there should be a clear reference of the pharmaceutical company responsible for providing the information while no disclaimer by the pharmaceutical company is permitted for the information included in the information campaign. Finally, the texts and graphs prepared should be signed by the physician of the pharmaceutical company in charge, whose name will be notified to the EOF.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Currently, there are no specific rules with regard to the use of social media by companies. However, the SFEE's Code of Ethics provides specific guidance to its members suggesting that in any case, the decision to create corporate Facebook pages/Twitter accounts and the approval of their content must go through the internal approval procedure of each company by an authorised team comprising members from all departments involved (e.g. Medical Affairs, Pharmacovigilance, Marketing, Compliance, Legal Department, E-business, Communications), so as to ensure the quality and validity of the information transmitted outwards in accordance with the applicable legislative provisions on the information and promotion of medicinal products to healthcare professionals by pharmaceutical companies and on public information with regard to diseases.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The EOF's circular no 44787/12.5.2017 on advertising of medicinal products was amended by circular no 16251/13.2.2019.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

In view of the recent amendments of EOF's respective circulars as mentioned above, amendments are expected with regard to the SFEE's Code of Ethics.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Over the past few years, the EOF has been actively updating its respective circulars with regard to the organisation of scientific events, sponsoring of HCPs and advertising of medicinal products. In this direction, pharmaceutical companies in Greece seem to enhance their internal compliance procedures in order to fully comply at all times with the existing legal and regulatory framework regarding the promotion and advertising of medicinal products, as well as organising and sponsoring scientific events.

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She is a recent graduate from Stanford University, and has accomplished a professional diploma in Intellectual Property Law and attended intensive and certified by IAPP courses regarding the new General Data Protection Regulation EU 679/2016 (GDPR) & Privacy Program management. Ioanna has also been certified by the Centre for Health, Pharmaceutical Law and Policy of Seton Hall University, USA, regarding Compliance, Moral and Regular Framework cases.

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During her postgraduate degree, she focused her research on Commercial and Competition Law, obtaining an LL.M. from Sorbonne University/Paris I, following her LL.B. from Dimokrition University of Thrace in Greece. Whilst at the Greek Consulate in Paris, she dealt with several legal cases in the fields of Corporate & Commercial, Intellectual Property & Data Protection Law both in Paris (BCW & Associates) and in Athens before joining Michalopoulou & Associates.

Ioli is committed to offering her legal services, with utmost concentration, professionalism and devotion setting the clients' interests as a top priority.

She is a contributor to *Legal X-rays* as a dedicated Health Law e-magazine and a speaker at Health Data conferences.

MICHALOPOULOU & ASSOCIATES
Law under the microscope

Michalopoulou & Associates lawgroup prides itself on the exceptional talent of its team of professionals; individually, they have developed significant legal experience working for international law firms, multinational corporations in the medical, life sciences and pharmaceutical industries and a vast array of private and public organisations.

Overall, and in the last 15 years, Michalopoulou & Associates have evolved into a specialised legal services firm to multinational companies, providing solutions and maximising client investments in the Medical, Pharmaceutical and Life Sciences industries – in areas such as data protection, compliance and corporate governance issues, anti-bribery, e-Health, pharmaceutical cannabis, clinical trials, intellectual property, public procurement, antitrust & parallel trade, biotechnologies, marketing practices, reimbursement, medical devices, malpractice and product liability.

The firm has delivered excellence through sophisticated legal services and successfully fulfilled disparate business or individual needs, putting the law under the microscope and the client first – at every stage of the legal process.

Chapter 15

# India


Aditi Subramaniam

Sanuj Das

Subramaniam & Associates (SNA)


## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The following two codified pieces of legislation control pharmaceutical advertising in India:

1. the Drugs and Cosmetics Act, 1940, which regulates the import, manufacture, distribution and sale of drugs and cosmetics; and
2. the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, which allows for the screening of advertisements or promotional material of any kind that attempts to sell drugs or remedies on the basis that they contain "magical" or "miraculous" properties.

In addition, the Consumer Protection Act, 1986, while not specifically aimed at the pharmaceutical industry, prohibits "unfair trade practices", which it defines as "a trade practice which, for the purpose of promoting the sale, use or supply of any goods or for the provision of any service, adopts any unfair method or unfair or deceptive practice". The Act further states that this definition includes unfair advertising. In addition, the Monopolies and Restrictive Trade Practices Act, 1969, prohibits advertisements which disparage another person's products.

Other than statutory control, Indian pharmaceutical advertising is regulated to some extent by the following:

1. The Department of Pharmaceuticals, run by the Ministry of Chemicals and Fertilizers, developed a Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) which is a voluntary Code that took effect from January 2015. The government expressed its intention to make this a statutory Code if implementation or adoption by pharmaceutical companies was unsatisfactory. In the fourth quarter of 2015, the Government announced that 2016 would see the incorporation of the UCPMP into statute. This has not yet materialised. In August 2016, the Department released a "clarification" stating that the UCPMP (which also covers the medical devices industry, according to the clarification) continues to be in effect as a voluntary Code until further notice.
2. In the context of the relationship or the association of pharmaceutical companies with healthcare professionals, the UCPMP also specifies that if a specific issue has not been addressed by the UCPMP, the statutory Code of the Medical Council of India – the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 must be consulted and adhered to.
3. The Code of Pharmaceutical Practices, developed by the Organisation of Pharmaceutical Producers of India (OPPI) in 2012. The OPPI is a non-governmental organisation consisting of representation from research-driven pharmaceutical companies. Its Code of Pharmaceutical Practices is based on the Code of Practice set out by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The OPPI Code applies only to OPPI members.
4. The Advertising Standards Council of India, which is a self-regulatory and voluntary organisation, has adopted a Code for self-regulation in advertising. While neither the organisation nor its Code pertains specifically to pharmaceutical products, the overarching aim of the Council is to promote honest advertising and fair competition.

### 1.2 How is "advertising" defined?

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, defines an "advertisement" as follows:

> "Advertisement includes any notice, circular, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke."

The Organisation of Pharmaceutical Producers of India (OPPI) does not define either "advertising" or "advertisement" but defines "promotion" as follows:

> "Promotion means any activity undertaken, organised or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet and mobile SMS, etc."

The Advertising Standards Council of India defines an "advertisement" as follows:

> "An advertisement is defined as a paid-for communication, addressed to the Public or a section of it, the purpose of which is to influence the opinions or behaviour of those to whom it is addressed. Any communication which in the normal course would be recognised as an advertisement by the general public would be included in this definition even if it is carried free-of-charge for any reason."

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The UCPMP prescribes that the Code itself be uploaded to the website of every pharmaceutical association, which must then set up

a committee (Ethics Committee for Pharmaceutical Marketing Practices, or the ECPMP) to monitor and handle any complaints regarding breach of the Code by a company. Further, the websites in question must remain updated with not only details of such complaints, but also the action taken by the committee in question to address the issue.

Although it is the job of the ECPMP to keep a check on any reported contravention of the law or ethics, the UCPMP also states that the Managing Director or CEO of every company is ultimately responsible for adherence to the Code. It is also the responsibility of the Managing Director or CEO, or the executive head of the company, to submit to the pharmaceutical association of which its company is a member, a declaration in its name confirming the company's adherence to the Code. This was required to be submitted first within two months of the initial date of issue of the UCPMP, and subsequently at the end of every financial year. The UCPMP also stated that these declarations are to be uploaded to the company websites.

The Code of Pharmaceutical Practices developed by the Organisation of Pharmaceutical Producers of India (OPPI) states in Section 11.1 that "[c]ompanies should establish and maintain appropriate procedures to ensure compliance with relevant Codes and applicable laws and to review and monitor all of their activities and materials in that regard".

The Code further states in Section 11.3 that "[a] designated company employee, with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel".

Apart from this recognition by the OPPI for a need to make arrangements to ensure compliance, neither available legislation nor the other Codes of practice contain specific guidelines on arrangements that companies or manufacturers are expected to make to ensure compliance with the law.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

Neither available legislation nor the Codes of practice contain any specific standard operating procedures. However, the UCPMP does mention the following:

1. that any promotion must be consistent with the terms of the marketing approval of the drug;
2. that any information provided in the advertisements must be up to date and verifiable, and must accurately reflect current knowledge or responsible opinion;
3. that any information about drugs must be accurate, balanced, fair, objective and must not mislead either directly or by implication;
4. that all information provided must be capable of substantiation; and
5. that if said substantiation is requested, it must be provided (at the request of members of the medical or pharmaceutical professions) without delay.

In a section called "Mode of Operation", the UCPMP also provides for the setting up of the ECPMP (please see questions 1.3 and 1.6) and the AECPMP (please see question 1.6). It prescribes that the UCPMP itself be published on the website of every pharmaceutical association, and that said website also contains updated details on complaints handled by the two aforementioned committees and the action taken by these committees in respect of said complaints.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

The pharmaceutical product must be pre-authorised for marketing for the specific use being advertised. However, the advertising material or content of the advertisement itself does not need to be pre-approved. The current patchwork of laws and Codes does not provide for such pre-approval even under certain specific circumstances.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, states that a Gazetted Officer authorised by the State Government may order the prevention of further publication of an advertisement that is found to contravene the provisions of the Act. Further, the Act grants said Officer the power to seize "documents, articles or things which contain any such advertisements". The provisions of the Code of Criminal Procedure apply to the search for and seizure of offensive material, and therefore the prosecution and appeal procedures are similar to those followed for any other criminal offence. The Act is silent on the issuing of corrective statements.

The UCPMP prescribes that the ECPMP of the relevant pharmaceutical association (please see question 1.3) must handle complaints against companies allegedly in breach of the Code. The ECPMP and its review committee (for appeals) called the Apex Ethics Committee for Pharmaceutical Marketing Practices, or the AECPMP, have the power to decide that an advertisement is in breach of the Code. These two committees may require (among other directions, such as the suspension or expulsion of the company from the Association, or the issuance and publication of a reprimand) the company to issue a corrective statement in the media (covering all media) which was used to issue promotional textual and audio visual details of the content in breach. The mode and timing of the dissemination of the corrective statement must be provided by the company to the committee for approval.

The OPPI Code provides for the setting up of an adjudicating panel, or a Secretariat, to review complaints of practices which violate said Code. The Code prescribes that the Secretariat must dispose of all complaints within 30 days of their being lodged. Possible sanctions include orders to issue "retraction statements". In addition, orders to the convicted party to issue statements in writing promising to discontinue the offensive advertisement may also be issued. However, since the OPPI Code lacks legislative force, the extent of penal action taken by its Secretariat is limited to expulsion of the convicted party from the organisation. Appeals are handled by a Board of five members, which arrives at a decision based on a majority vote.

In addition, although it does not pertain specifically to the pharmaceutical industry, the self-regulatory Code of the Advertising Standards Council of India (ASCI) also covers wrongful advertising in the pharmaceutical sector. The Code states that "if the complaint is upheld then the advertisement will need to be modified or pulled out, as is applicable for all complaints". The Code does not specifically provide for the issuing of corrective statements. As far as the appeals procedure is concerned, the general procedure for

dealing with complaints against purportedly offensive or misleading advertisements is that the ASCI reviews and decides all cases and refers appeals to its Consumer Complaints Council (CCC) for adjudication.

The Consumer Protection Act, 1986, while also aimed at consumer protection in general rather than consumers specifically in the pharmaceutical industry, provides for the issuing of a "corrective advertisement" at the cost of the offending party to cancel or neutralise the effect of a misleading advertisement. The decision to issue the corrective advertisement is made by a "district forum", and the defendant is granted the right to appeal the decision of the district forum. The hierarchy for appeal begins with the State Commission, followed by the National Commission, both of whose benches are comprised of judges of the High Court and Supreme Court, respectively, along with at least two other members each. The final platform for appeal is the Supreme Court.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, provides in Section 7 that those found in contravention of the provisions of the Act shall, on conviction, be punishable:

a) in the case of a first conviction, with imprisonment which may extend to six months, or with a fine, or both; or

b) in the case of a subsequent conviction, with imprisonment which may extend to one year, or with a fine, or both.

The Act also states that "no Court inferior to that of a Presidency Magistrate or a Magistrate of the first class shall try any offence punishable under this Act".

Responsibility for the enforcement of decisions of the court under The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, lies with Gazetted Officers authorised by the State Government. The Department of Pharmaceuticals, the Advertising Standards Council of India (ASCI) and the Organisation of Pharmaceutical Producers of India (OPPI) also routinely enforce their Codes of practice and by extension, available legislation, via their complaint redressal mechanisms as detailed above. Penalties enforced by these organisations vary from instructions to the convicted party to issue "retraction" or "corrective" statements, or, in the case of the OPPI, expulsion from the organisation itself.

For the penalties prescribed by the UCPMP, refer to question 1.6 above. There have been no cases of any action being taken against pharmaceutical companies for not adhering to the relevant Codes – the Indian jurisdiction is nascent in this respect.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

To a very large extent, the regulation of pharmaceutical advertising is carried out by self-regulatory bodies, particularly the OPPI and the ASCI, and these organisations tend to be the first platform of litigation for most complainants, who are largely competing pharmaceutical companies. If either party is displeased with the conclusion arrived at by adjudicating bodies in their self-regulatory organisation of choice, the option to proceed to court is certainly available to both parties. In addition, the government may step in if serious violations occur, although this rarely, if ever, happens. Although the burden to regulate adherence to the UCPMP is on the various Pharmaceutical Associations and also on the Managing Directors or CEOs of companies, the government has noticed a shocking lack of compliance with the Code, and proposes to amend the Code to make it mandatory. It is, however, at the current date, still a voluntary Code.

Competent authorities, such as higher courts of law, are certainly permitted to, and do in practice, investigate matters which constitute both a breach of relevant Codes as well as of the law, when such matters are brought to their attention.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The Competition Act, 2002, provides for the filing of actions in tort against unfair competition and allows injured parties, or parties who believe they have reason to fear injury from damage caused to them by unfair competition, to file said actions.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

The UCPMP clearly states that no pharmaceutical products may be promoted prior to receipt of the product authorisation, which permits its sale or supply. In addition, the OPPI Code similarly states that no pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.

However, the OPPI Code further emphasises that these provisions are not intended to prevent the right of the scientific community and the public to be fully informed of scientific and medical progress, neither are these rules intended to restrict a full and proper exchange of scientific information concerning pharmaceutical products, said exchanges including appropriate dissemination of investigational findings in scientific communities, lay communications, the media and at scientific conferences.

Presumably, therefore, information may be discussed at scientific meetings and made available to healthcare professionals on the condition that information on unauthorised drugs is the dissemination of scientific knowledge rather than promotional material.

While the Codes and legislation are silent specifically on the ethical concerns at meetings sponsored by pharmaceutical companies, clause 3.3 of the Voluntary Code of Marketing Practices for the Indian Pharmaceutical Industry developed by the Department of

Pharmaceuticals does state that promotional material, such as mailings and journal advertisements, must not be designed to "disguise their real nature". Where a pharmaceutical company pays for, or otherwise secures or arranges, the publication of promotional material in journals, such promotional material must not resemble editorial matter. This suggests that although sponsored meetings and dissemination of relevant information at those meetings are permissible, healthcare professionals must be made aware of the potential commercial interests being pursued by pharmaceutical companies at these meetings.

In addition, the OPPI Code states that "the purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings for healthcare professionals, organised or sponsored by a company, should be to inform healthcare professionals about products/therapy, and/or to provide scientific or educational information".

The OPPI Code also states the following:

> "Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:
>
> - the meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place;
> - promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and making clear that such product is not available locally;
> - promotional material which refers to the prescribing information (indications, warnings, etc.) authorised in a country or countries other than that in which the event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
> - an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally."

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

The information on unauthorised medicines and/or off-label information may be published, as long as such publication is in a scientific document or journal, or a patent specification or research paper, and as long as the publication is not for promotional purposes.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Press releases about unauthorised medicinal or pharmaceutical products and/or off-label products are clearly prohibited by both the available Codes of practice as well as the law. This prohibition applies regardless of the intended audience.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

No information on unauthorised drugs may be sent by companies to healthcare professionals (or any member of the public, for that matter). The Codes of practice of self-regulatory bodies and the available legislation are both silent on the ethical questions of whether healthcare professionals are permitted to request such information, however.

The OPPI Code as well as the UCPMP both state clearly that once drugs have been authorised for sale and supply, healthcare professionals have the right to demand substantiation of promotional material from the companies in question, which the companies must then provide.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Neither Indian legislation nor the Codes have so far been amended to reflect the change in European law that the *Ludwigs* judgment brought about. To make said price-lists available to pharmacists would still be treated as illegal advertising in India.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Presumably not. However, the legislation and Codes of practice of self-regulatory bodies do not specifically deal with this issue.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The OPPI Code states that member companies of the OPPI may engage a medical practitioner in advisory capacities – including, among other capacities, as researchers – provided that in doing so, the member company shall always:

1. ensure that the healthcare professional's integrity and freedom is not compromised;
2. ensure that patients' interests are not compromised in any way;
3. ensure that such affiliations are within the law; and
4. ensure that such affiliations/employments are fully transparent and disclosed, wherever required under law.

The Code also states that healthcare professionals may be engaged for participation in market research where such participation involves remuneration. The arrangements which cover these services must, to the extent relevant to the particular arrangement, fulfil all of the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services, which specifies the nature

of the services to be provided and the basis for payment of those services;

- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of a consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and
- the compensation for the services must be reasonable and reflect the fair market value of the services provided.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

The UCPMP states that where the purpose of promotional material is to provide persons qualified to prescribe or supply drugs (i.e. healthcare professionals) with sufficient information for prescription or for use, the following minimum information must be given clearly and legibly, and must be an integral part of the advertisement:

- the relevant product authorisation number and the name and address of the holder of the authorisation, or the business name and address of the part of the business responsible for placing the medicinal product on the market;
- the name of the product. In addition, a list of the active ingredients (using common names) must be placed immediately adjacent to the most prominent display of the name of the product;
- the recommended dosage, method of use and, where it is not obvious, the method of administration;
- possible adverse reactions, warnings and precautions for use and relevant contraindications of the product;
- a statement that additional information is available on request; and
- the date on which the above particulars were generated or last updated.

The OPPI Code provides very similar guidelines for the information that must be made available in promotional material and advertisements to healthcare professionals. In addition, the Code also allows for the provision of "reminder advertisements", which are defined as short advertisements which contain simply the name of the product with a statement of indications.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

The OPPI and UCPMP both restrict the promotion of any information on products that have not been authorised or are yet to be authorised for sale or supply. There are no references to information or studies not part of the summary of product characteristics. Unlike the European Union, the Indian government has not yet provided a guideline on the SmPC.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The UCPMP states that the names or photographs of healthcare professionals must not be used in promotional material. In addition, the OPPI Code states that no financial incentive may be offered to healthcare professionals to recommend pharmaceutical products in any way, and also that healthcare professionals should not be influenced to endorse any drug or product of any pharmaceutical company publicly.

The Code of Ethics Regulations, 2002, published by the Secretary of the Medical Council of India, also states that no healthcare professional may publicly endorse any pharmaceutical product.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

The clinical trials protocol depends upon the nature of the drug in question. In some cases, trials with animal models are acceptable, while in other cases human trials may be required. Yet in some cases, as in the case of HIV, human trials are not permitted. From an advertising point of view, there is no particular number of "head to head" clinical trials prescribed for making comparative claims, although it may be necessary to obtain a marketing or manufacturing licence for a new drug. However, while such comparative claims are permitted, other legislations, for instance, the Patents Act or the Monopolies and Restrictive Trade Practices Act, may disallow an advertisement which specifically disparages another product or brand even through comparative data.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

The UCPMP states that:

- Comparisons of medicinal products must be factual, fair and capable of substantiation.
- In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission or in any other way.
- Brand names of products of other companies must not be used in comparison unless the prior consent of the companies concerned has been obtained.
- Other companies, their products, services or promotions must not be disparaged either directly or by implication.

In addition, the OPPI Code allows for comparisons to be made as long as any comparison made between different pharmaceutical products is based on relevant and comparable aspects of the products and is capable of substantiation. The Code also states that comparative advertising should not be misleading.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

Both available legislation as well as the Codes of practice are silent on this issue. Generally, what is not specifically prohibited is permitted.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Both available legislation and the Codes of practice are silent on this issue. Generally, what is not specifically prohibited is permitted unless a question of morality is involved. Going by the practice in trade and commerce, teaser advertisements would likely be allowable.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Neither legislation nor current Codes of practice provide guidelines on the application or use of the SmPC in India. As explained in the answer to question 3.1, there is certain minimum information that must be provided to healthcare professionals under the UCPMP. This is particularly true when such information is part of promotional material which will assist professionals in prescribing the product in question. This minimum information includes recommended dosage and method of use. Presumably, the UCPMP would therefore require that the SmPC for Product B expressly refer to combination use with Product A. Further, the interpretation of the law by a well-informed court would likely be that the holder of the MA for Product B must first vary the SmPC for Product B before promoting combination use. The lack of jurisprudence or regulation on the matter makes it difficult to predict whether a court of law or regulatory enforcement authority would require the holder of the MA for Product A also to refrain from promoting combination use before Product B's SmPC has been varied. However, given the legal uncertainty on the subject, this would certainly be the recommended route.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

According to the UCPMP, free samples of medicinal products shall not be supplied to any person who is not qualified to prescribe such product.

The UCPMP further states that where samples of products are distributed by a medical representative, the sample must be handed directly to persons qualified to prescribe such products, or to persons authorised to receive the sample on their behalf.

The UCPMP states that the following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:

i. such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product;

ii. such sample packs shall be limited to prescribed dosages for three patients for a required course of treatment;

iii. any supply of such samples must be in response to a signed and dated request from the recipient;

iv. an adequate system of control and accountability must be maintained in respect of the supply of such samples;

v. each sample pack shall not be larger than the smallest pack presented in the market;

vi. each sample shall be marked "free medical sample – not for sale" or bear another legend of analogous meaning; and

vii. each sample shall be accompanied by a copy of the most up-to-date version of the Product Information (as required by the Drug and Cosmetics Act, 1940) relating to that product.

The supply of samples of anti-depressants, hypnotics, sedatives or tranquillisers is prohibited by the Code. Further, the Code also requires that companies maintain a detailed record of free samples distributed to healthcare practitioners.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

The Code of the OPPI and the UCPMP both clearly prohibit any gifts or donations to healthcare professionals. The Code of Ethics Regulations, 2002, published by the Medical Council of India, also prohibits healthcare professionals from giving, soliciting or accepting any gifts or donations of any kind.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

While the Codes or the legislation do not specifically mention the giving of gifts or donations to healthcare organisations, the UCPMP does state the following:

> "**No gifts, pecuniary advantages or benefits in kind** may be supplied, offered or promised to **persons qualified to prescribe or supply drugs**, by a pharmaceutical company or any of its agents, i.e. distributors, wholesalers, retailers, etc." (Emphasis added.)

While organisations are not specifically mentioned, the inference that this clause includes donations made to organisations is made stronger by the fact that a second clause exists, specifically prohibiting the giving of gifts for the "personal benefit" of healthcare professionals and their family members. Arguably, this clause would not be required if the first clause referred only to them and did not include donations made to organisations.

The donation of equipment or the funding of technical or medical services are presumably not permissible if they are part of promotional campaigns or advertisements of any kind. There has been no litigation on this subject, but it has been speculated that the Government's notice expressing its intention to make the UCPMP mandatory this year was fuelled in part by the practice of making donations or giving gifts to healthcare organisations and professionals by pharmaceutical companies, which is certainly frowned upon.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

No, the provision of goods or services which influence prescription patterns is not permissible. The OPPI Code states that nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices, or would influence their professional integrity and autonomy or will compromise patients' interests in any manner.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Presumably, if the offer of volume-related discounts does not violate general commercial legislation, such as legislation governing unfair trade practices, such discounts ought not to be objectionable. The Codes of practice and legislation on pharmaceutical advertising are silent on this issue.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

No. The UCPMP states that companies or their associations or representative shall not pay any cash or monetary grants to healthcare professionals for individual purposes in their individual capacity on any pretext. Further, the OPPI Code states that no financial benefit or benefit in kind, may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

The available legislation and Codes of practice contain no references to refund schemes.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes. The UCPMP states that companies may legitimately provide funding for medical research, study, etc., but that this can be done only through approved institutions, by modalities laid down by the law/rules/guidelines adopted by such approved institutions. Further, this must be entirely transparent and "always be fully disclosed". The mode of disclosure is not specified.

The OPPI Code states that Continuing Medical Education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. However, when companies provide content to CME activities and programmes, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognised opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Litigation with respect to bribery and corruption in India has pertained mainly to public procurement, with no judicial precedent of the application of our anti-corruption laws to the sector of pharmaceutical advertising. In theory, however, the provisions of the Indian Penal Code, 1860 and the Prevention of Corruption Act, 1968, would apply to criminal proceedings relating to corruption in the pharmaceutical sector. Arguably, such matters could also be brought before the Competition Commission of India under the Competition Act, 2002, on the grounds of anti-competitive practices.

Unfortunately, as no such litigation has as yet occurred, it is difficult to ascertain the dynamic between anti-corruption officials and the competent authorities within the pharmaceutical sector. Though not specific to pharmaceutical advertising, an example of pharmaceutical competent authorities working simultaneously to anti-corruption officials was available in the case of Dr. Ketan Desai, a prominent urologist who was brought before the High Court several times by the Central Bureau of Investigation on serious corruption charges. As the criminal proceedings were under way, the Medical Council of India took cognisance of the matter and revoked the doctor's licence *suo moto*. It is pertinent to mention that Dr. Desai has twice held the position of the President of the Medical Council of India. Please see the answer to question 1.8 for more details.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The Medical Council of India amended its Code of Ethics in 2010 to ban the provision of hospitality by pharmaceutical companies to healthcare professionals. The UCPMP also states that companies or

their associations or representative shall not extend any hospitality to healthcare practitioners and their family members under any pretext whatsoever.

The OPPI, however, states that member companies may not provide hospitality to healthcare professionals, unless said professional is engaged by the company in an advisory capacity, such as, for instance, a consultant, researcher, treating doctors or any other professional capacity. In such an engagement, the Code states that a member company must always:

i. ensure that the healthcare professional's integrity and freedom is not compromised;

ii. ensure that patients' interests are not compromised in any way;

iii. ensure that such affiliations are within the law; and

iv. ensure that such affiliations/employments are fully transparent and disclosed, wherever required under law.

The Code also states that the hospitality arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all of the following criteria:

i. a written contract or agreement must be agreed in advance of the commencement of the services, which specifies the nature of the services to be provided and the basis for payment of those services;

ii. a legitimate need for the services must be clearly identified and documented in advance;

iii. the criteria for selecting consultants must be directly related to the identified need, and the consultants must have the expertise necessary to provide the service;

iv. the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;

v. the hiring of a consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and

vi. the compensation for the services must be reasonable and reflect the fair market value of the services provided.

Having said that, since the OPPI is a private body (albeit with considerable influence) and the UCPMP is a government drafted Code, despite being voluntary, the latter is likely to override the former.

Available legislation and all the self-regulatory Codes do not deal with hospitality arrangements abroad.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The UCPMP prohibits payments or gifts (including offering hotel accommodation, cash or monetary grants) to healthcare professionals under any pretext. Presumably, this also includes reimbursement for travel/accommodation/enrolment fees for scientific meetings. However, this has not been specified in the Code or legislation.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Pharmaceutical companies are expected to fully comply with the requirements of the OPPI Code and the UCPMP as described in the answer to question 5.1. This is equally applicable to meetings directly organised by the companies as well as those in which they provide partial sponsorship. Non-compliance with said requirements is therefore dealt with in a manner appropriate to the degree of non-compliance and the perceived consequences of said non-compliance.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

See question 2.7 above.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

It is possible, as long as such acts do not violate a professional's employment contract or their own professional Code of Conduct under the applicable law. The OPPI Code, the UCPMP and the statutes are all silent on this.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

See question 2.7 above.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes. The UCPMP applies to marketing practices for all drugs manufactured by pharmaceutical companies. No specific restrictions have been detailed for the advertisement of non-prescription drugs in the Code, which means that the general standards and restrictions set out for promotion and marketing in the Code will apply to non-prescription drugs as well.

The OPPI Code does not apply to the advertisement of non-prescription drugs. Non-prescription or OTC drugs exist mainly as a negative list in India, i.e., those drugs which are not listed as prescription medications are automatically non-prescription medicines. General rules of fairness, accuracy and balance as established in the Code of The Advertising Standards Council of India (which applies to all advertising, and not specifically to pharmaceutical promotional material) apply in this context as well.

The advertisement of non-prescription drugs is also subject to restrictions under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, which prohibits advertisements or promotional material of any kind that attempt to sell drugs or remedies on the basis that they contain "magical" or "miraculous" properties. The aim behind the drafting of this Act is to prevent the public from self-medicating with non-prescription drugs under the influence of misleading and/or partially or wholly inaccurate advertising.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

No. Prescription-only medication is listed in Schedules H and X of the Drugs and Cosmetics Act, 1940, and the Act strictly prohibits the

advertisement of said drugs. However, the advertisement of Ayurvedic and Homeopathic medication is permissible, although either type of medication may, in some cases, require prescriptions.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are not specifically mentioned in the available Codes of practice or legislation. Further, the OPPI does not cover the advertising of prescription medication directly to consumers. The OPPI says merely the following with regard to disease awareness campaigns:

> "The OPPI Code covers interactions with healthcare professionals, medical institutions and patient organisations, and the promotion of pharmaceutical products. A public disease awareness campaign targeted at the public must not promote specific pharmaceutical products. Whilst not covered by the OPPI Code, disease awareness campaigns must of course comply with local laws, regulations, and/or Codes."

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Since the advertisement of prescription medication to the general public is strictly prohibited by The Drugs and Cosmetics Act, 1940, press releases in non-scientific journals are not permissible under the law. The available Codes and statutes only permit advertisement of authorised drugs in specific situations, and therefore press releases for unauthorised medicines or indications would be illegal.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Every piece of literature that is disseminated to the public is subject to The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, which allows for the screening of advertisements or promotional material of any kind that attempts to sell drugs or remedies on the basis that they contain "magical" or "miraculous" properties. The data must be credible and be based on actual research and should be capable of withstanding scrutiny by a court of law. They should not disparage another person, product or brand.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

According to the OPPI Code, when working with patient organisations, companies must ensure that the involvement of the company and the nature of that involvement are clear from the outset. No company is permitted to demand that it be the sole funder of the patient organisation or any of its programmes.

The Code also states that companies that provide financial support or contributions in kind to patient organisations must have in place written documentation setting out the nature of the support, including the purpose of any activity and its funding.

Further, companies may provide financial support for patient organisation meetings provided that the primary purpose of the meeting is professional, educational and scientific in nature, or that the meeting otherwise supports the mission of the patient organisation. When companies hold meetings for patient organisations, the Code requires the companies to ensure that the venue and location is "appropriate" and "conducive to" informational communication. In addition, any meals or refreshments provided by a company must be "modest as judged by local standards".

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The UCPMP is silent on this. For information on the full extent of available guidelines on what may or may not be provided to patients by companies, refer to question 6.6 above.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

There is no obligation under any laws which regulate advertisements to disclose ongoing and/or completed clinical trials. However, there is indeed an obligation under our regulatory laws to make full disclosure of the clinical trials for the purposes of obtaining regulatory approvals. The OPPI Code states that its member companies are committed to the transparency of clinical trials which they sponsor. It is recognised that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. The Code states that such disclosure, however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010) issued by the IFPMA, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

No. In fact, neither the Codes drafted by self-regulatory bodies nor the legislative authorities have so far even implemented the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies and Healthcare Organisations.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

No. See question 7.2 above.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

See questions 7.1 and 7.2 above. Neither the Codes nor legislation provide any information about transfers of value by companies.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

In August 2018, the Ministry of Health and Family Welfare released a draft of rules to amend the Drugs and Cosmetics Rules, 1945, proposed in exercise of the powers conferred by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940. The draft rules were written in consultation with the Drugs Technical Advisory Board, and are aimed at covering the sale of pharmaceutical products online via "e-pharmacies". The draft rules address various issues, including the registration of e-pharmacies, the validity of the licence to make online sales, patient confidentiality and records maintained by e-pharmacies. On the subject of advertising, the draft rules state only the following:

> "Prohibition of advertisement of drugs through e-pharmacy: No e-pharmacy shall advertise any drug on radio or television or internet or print or any other media for any purpose."

The draft rules have not yet passed into law. In the meantime, neither the current legislation nor the Codes of practice contain any other provisions specific to advertising on the internet. The Information Technology Act, 2000 ("the IT Act") which is a general piece of legislation broadly regulating all activity on the internet, would also apply to any commercial activity relating to pharmaceutical products on the internet. However, the IT Act does not contain provisions directed specifically to this issue.

The Delhi High Court has recently banned the sale of any medicines over the internet by e-pharmacies. The order directs the central government as well as the state of Delhi to restrain such sales on the basis that the Drugs and Cosmetics Act, 1940 and the Pharmacy Act, 1948, do not envisage or permit the sale of medicines online. The interim order imposing the ban was passed in response to public interest litigation that alleged that online sales of medicines are unrestricted and unregulated. The petitioners pled that there is no legal framework requiring e-pharmacies to obtain licences for sale in the manner that traditional real-world druggists, chemists and pharmacies must do. Evidence was also presented before the court to demonstrate the serious risk to public health, particularly in rural areas, posed by the sale of medicines over the internet without verifiable prescriptions and by unlicensed vendors, as well as by the online sale of medicines which are otherwise spurious, dangerous or addictive.

The Chennai High Court has also banned the online sale of medicines. Both orders render the unlicensed sale of medicines over the internet illegal and shall stay in force until the draft rules are passed into law. Presumably, although neither order refers specifically to online advertisements and promotions, such activities are also illegal to the extent that they may not be carried out by e-pharmacies, especially because the draft rules prohibit such promotion in any case.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

The available Codes of practice as well as the available legislation are both silent on this issue.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Neither the available legislation – both that pertaining to pharmaceutical advertising as well as general cyber law – nor the Codes of conduct specify any information with respect to either reverse-linking to company websites or hyper-linking on company websites.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Neither the law nor the available Codes of practice prohibit the publishing of any information by companies on their websites for access by the general public, as long as said information pertains to pharmaceutical products which have been authorised for sale or supply.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The available Codes of practice as well as the available legislation are both silent on this.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

The draft rules pertaining to e-pharmacies and two High Court Orders restraining the sale of medicines online are two developments of great significance. See the answer to question 8.1 for details.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

The passage of the draft rules (referred to in the answers to questions 8.1 and 9.1) into law is likely to occur during the coming year.

The Department of Pharmaceuticals has over the last few years indicated that should the need to incorporate the UCPMP into law arise, it will do so, making it mandatory rather than voluntary, as it currently stands. However, no public notice has been issued to this effect thus far. It is not clear whether or not this will happen at all, although there has been a push for this development on the basis that the voluntary Code does not have the teeth to curb unethical practices and non-compliance, particularly with respect to gift-giving/provisions of hospitality to healthcare professionals by companies. It remains to be seen whether any change will occur in the coming months.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

There had been a tremendous rise in the sale of medicinal goods online until the issuance of two High Court orders banning such sales towards the end of 2018 (and earlier this year). It was estimated at the end of 2018 that online pharmacies cornered 140 million USD of the Indian drug market, and that this market share was steadily rising. The draft rules envisage the licensing of e-pharmacies, and in anticipation of the existing ban on online sales being lifted when the draft rules come into force, a large number of investors have raised millions of dollars' worth of capital for online healthcare and pharma aggregators, subscription-based online pharmacies and online medicine distributors. On the other hand, traditional, real world chemists and pharmacies, alleging that online sales pose unreasonably high risks to public health, have opposed such sales in several states, including Delhi, Chennai, Karnataka and Maharashtra.

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# Ireland

Colin Kavanagh

Arthur Cox

Bridget McGrath

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products is governed by a combination of legislation and self-regulatory codes of practice. The principal regulations are the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007) (the "Regulations"), which implement Titles VIII and VIIIa of Directive 2001/83/EC (as amended) (the "Directive"). In addition, general laws concerning advertising and commercial practices are set out in the Consumer Protection Act 2007 (the "CPA") and the European Communities (Misleading and Comparative Marketing Communications) Regulations 2007 (the "Misleading Advertising Regulations"). The Ethics in Public Office Acts, 1995 and 2001 (as amended) (the "Ethics Acts"), apply to promotional practices involving healthcare professionals who also hold certain designated public positions or directorships. The Criminal Justice (Corruption Offences) Act 2018 (the "2018 Act") may also apply in circumstances where promotional practices are found to be corrupt.

The Health Products Regulatory Authority (the "HPRA") is the body responsible for monitoring the advertising of medicinal products and enforcing the Regulations. The Competition and Consumer Protection Commission is the regulatory body with oversight of general consumer law, while the Broadcasting Authority of Ireland is the regulator for radio and television broadcasts in Ireland.

The law is supplemented by a number of codes of practice. The Irish Pharmaceutical Healthcare Association ("IPHA"), the industry body representing the international research-based pharmaceutical industry in Ireland, has published two relevant codes of practice: the IPHA Code of Practice for the Pharmaceutical Industry (Edition 8.4) (the "Pharmaceutical Code"); and the IPHA Code of Standards of Advertising Practice for the Consumer Healthcare Industry (Revision 5.2, 2017) (the "Consumer Code") (together the "Codes"). These Codes apply only to those pharmaceutical companies that have voluntarily agreed to be members of the IPHA. The Advertising Standards Authority for Ireland ("ASAI"), the independent self-regulatory body for the advertising industry, has issued a "Code of Standards for Advertising and Marketing Communications in Ireland" (7th Edition) ("ASAI Code"), which applies to advertising generally, while the Broadcasting Authority of Ireland has produced a "General Commercial Communications Code" (the "BAI Code"), which applies to advertising broadcasts on radio or television channels licensed in Ireland.

### 1.2 How is "advertising" defined?

"Advertising" is defined in the Regulations as any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. This specifically includes:

- advertising to the general public and those who are qualified to prescribe or supply medicinal products;
- supply of samples;
- inducements to prescribe or supply by the gift, offer or promise of any benefit or bonus, in money or in kind;
- sponsorship of promotional meetings and scientific conferences attended by persons qualified to prescribe or supply; and
- in particular, the payment of travelling and accommodation expenses associated with such conferences.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The Regulations require that a scientific service be established within the company to compile and collate all information relating to products. Medical sales representatives must be adequately trained and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about the product they are promoting. Companies must keep available samples of all advertising emanating from their undertaking together with information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination, and such information must be supplied to the HPRA upon request. The Pharmaceutical Code requires that the scientific service must include a doctor or, where appropriate, a pharmacist or other suitably qualified person who must approve all promotional material prior to release. Such person must certify that the advertisement complies with the Pharmaceutical Code and all applicable laws, is consistent with the relevant summary of product characteristics ("SmPC"), and is a fair and truthful presentation of the facts concerning the medicinal product being promoted. The Pharmaceutical Code requires that each company appoint at least one senior employee who is responsible for supervising compliance with the Pharmaceutical Code.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

There are no legal or code requirements for SOPs governing advertising activities. Under section 21.1 of the Pharmaceutical Code, every company must establish a Scientific Service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. This Scientific Service must include a medical doctor or, where appropriate, a pharmacist or other suitably qualified person who will be responsible for:

(i) approving any promotional material before release. Such person must certify that he or she has examined the final version of all promotional material and that, in his or her belief, it is in accordance with the requirements of the Pharmaceutical Code and any applicable advertising laws and regulations, is consistent with the relevant SmPC and is a fair and truthful presentation of the facts about the medicinal product being promoted; and

(ii) overseeing any non-interventional study. Such person must certify that he or she has examined the protocol relating to the non-interventional study, and that in his or her belief it is in accordance with the requirements of the Pharmaceutical Code.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

There is no necessity to have advertising pre-approved by a regulatory or industry authority. However, the HPRA reserves the right to pre-review advertisements.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The HPRA can order the withdrawal of a misleading advertisement and the issuing of a corrective statement in respect of a published advertisement. The Irish Courts can order the withdrawal of an advertisement and that a corrective statement be issued, where a party is convicted of a specified offence under the Irish Medicines Board Act 1995, as amended (the "IMB Act"), and the court is satisfied that the advertisement was misleading. The IPHA may require the withdrawal of an advertisement if it is of the opinion that it is not in the interests of consumer safety. Decisions of the IPHA Code Council may be appealed to the IPHA Appeals Board, and the decision of the IPHA Appeals Board is final and binding. Decisions of the HPRA may be appealed to the Irish Courts.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Penalties for breach of the Regulations range from a fine of up to €2,000 and/or imprisonment of up to 12 months on summary conviction, to a fine of up to €120,000 and/or a term of imprisonment of up to 10 years on indictment. On subsequent convictions, the maximum fine increases to €300,000. If an offence is committed by a body corporate, personal liability may apply to the officers. Prosecutions may be brought by the HPRA, the Minister for Health (the "Minister"), the Pharmaceutical Society of Ireland ("PSI") and the Health Service Executive ("HSE"). A competitor may inform any of the above bodies of non-compliant advertising.

Penalties for breach of the Pharmaceutical Code are dealt with by the "Code Council" of IPHA and range from: an order to cease the breach; a reprimand; an order for the recovery of offending material; publication of a corrective statement; publication of the decision; referral of the matter to the Minister; and suspension or expulsion from the IPHA. A competitor may inform the IPHA of non-compliant advertising.

Penalties for breach of the Misleading Advertising Regulations and the CPA consist of a fine of up to €3,000 and/or imprisonment not exceeding six months on summary conviction, a fine of up to €5,000 and/or imprisonment not exceeding 12 months for subsequent summary convictions, a fine of up to €60,000 and/or up to 18 months' imprisonment on a first conviction on indictment, a fine of up to €100,000 and/or up to 24 months' imprisonment for subsequent convictions on indictment, and a daily fine of up to €500 for each day that the contravention continues following summary conviction, with this daily fine rising to a maximum of €10,000 for each day that the contravention continues following conviction on indictment. The Misleading Advertising Regulations and the CPA allow a competitor to apply to court for an order preventing a company from engaging in misleading marketing or prohibited comparative advertising.

An interesting case which involved a serious breach of the IPHA Code occurred in 2015, when Shire advertised their product Buccolam Oromucosal Solution, which had appeared in the publicly available Irish Independent Newspaper Neurology Supplement on 4 December 2015. The breach of the Code and the breach of Regulation 9 of the Medicinal Products (Control of Advertising) Regulations 2007 had been notified to Shire by the HPRA, on foot of two complaints received by them following the publication of the advertisement. The Code Council was of the view that the advertisement of a prescription-only medicine to the public is an extremely grave matter. The Code Council believed that in the publication of this advertisement, proper procedures were not followed and this demonstrated a lack of control over the entire process within the organisation. Accordingly, the Code Council determined that the placing of the advertisement had reduced confidence in the pharmaceutical industry and thereby found a breach of Clause 2.1 of the Code. The Code Council required that Shire undertake an independent external audit of all their advertising/promotional procedures and processes (and compliance with those processes and procedures) within six months. Moreover, an annual audit is to be completed for a further three years to ensure continued compliance with all advertising/promotional procedures and processes.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The Codes fit into the framework established by Regulation 26 of the Regulations, which recognises the role of voluntary control in the advertising of medicinal products. Breaches of the Pharmaceutical Code are generally dealt with by the Code Council (please see questions 1.6 and 1.7 above); however, the IPHA may refer difficult or persistent breaches of the Codes to the Minister. IPHA may also advise the ASAI of its findings against an advertiser and recommend action. In addition, advertising is monitored and regulated by the HPRA. It supervises compliance with the Regulations by performing random reviews of advertisements in various media, including journal publications, newspapers, radio and television advertising. It may also carry out inspections at the offices of marketing authorisation holders ("MAH") which advertise human medicinal products, and investigate complaints received in relation to advertisements. If such investigations show non-compliance with the Regulations and/or the Codes, the HPRA will either require that the advertisement be corrected or, less frequently, take legal proceedings.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

An individual/company who believes that a particular company is engaging in unfair competition (as prohibited by the Competition Act 2002 (as amended)) may bring an action for damages in the courts. Alternatively, it may report the behaviour to the Competition and Consumer Protection Commission, which may bring an action on its own behalf. An individual/company who believes that a company has breached its intellectual property may bring a matter to the courts under legislation such as the Trade Marks Act 1996 (as amended) or through a number of actions such as passing off. Recourse for defamation is available by taking an action under the Defamation Act 2009.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

The Regulations prohibit promotion of medicinal products that are not the subject of a marketing authorisation or a certificate of traditional use registration (the latter registration relates to herbal medicinal products). The Codes also prohibit the promotion of products prior to authorisation, subject to certain exceptions such as materials at international congresses and symposia held within Ireland.

Separately, the CPA deems as a "prohibited commercial practice" a representation that a product has an authorisation which it does not have. Advertisements, as part of a vaccination campaign, however, are approved (provided the Minister has permitted the same). In addition, correspondence to healthcare professionals in response to an unsolicited specific question about a particular medicinal product, which may include material of a non-promotional nature, and non-promotional, generic information about companies, including financial data, descriptions of research and development programmes, and discussions of regulatory developments affecting the company and its products, are not prohibited. The Regulations prohibit the promotion by MAHs of medicinal products for therapeutic indications for which they have not been approved. However, the legitimate exchange of medical and scientific information to healthcare professionals is not prohibited, provided such information or activity does not constitute any form of promotion that would be prohibited under the Regulations. Scientific, complete, objective, factual and non-promotional information concerning the off-label use of the products may be provided to healthcare professionals by representatives of the medical departments in response to an unsolicited request by the healthcare professional for such information.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Indications for unauthorised medicinal products and off-label usage in Ireland may be referenced in promotional material appearing on exhibition stands or distributed at international congresses or symposia held in Ireland, provided such medicinal products and indications are in fact approved in at least one other country in the EEA. This exception applies only to meetings that are truly international and scientific. A clearly visible and legible statement must also be included, indicating that the material relates to a product or indication that is unapproved in Ireland. In addition, where prescribing information is provided, an explanatory statement must also be included indicating that licensing conditions differ internationally. If products are not approved in the EEA, no promotional material may be displayed or distributed, but legitimate, balanced and non-promotional scientific papers that include off-label information or information concerning unauthorised medicinal products may be provided at the medical booths at symposia or conferences in response to an unsolicited request from a healthcare professional for that specific information. Such information must not be distributed along with promotional materials or contain references to promotional materials. In addition, such information should not be distributed to patients or members of the general public.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

The Regulations do not deal specifically with press releases. The Pharmaceutical Code, however, defines press releases as a form of promotion, and therefore the same requirements apply to press

releases and media statements as any other promotional material. Nevertheless, the Pharmaceutical Code also indicates that information about a scientific discovery of an investigational product may be supplied where it is desirable or necessary to do so in the public interest. This may also apply where the object is to inform the public of scientific and medical progress, or where it is required or desirable to provide information to the public as shareholders or as persons with some other special or valid interest. In such circumstances, press releases are permitted. Care must be taken, however, not to include any information that could be perceived as direct to consumer promotion of an unauthorised product.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Scientific, complete, objective, factual and non-promotional information concerning the off-label use of the products or unauthorised products can be provided to healthcare professionals in response to an unsolicited and specific request by the healthcare professional for such information. MAHs are not permitted to proactively distribute such information to healthcare professionals. In addition, such correspondence may only be distributed to healthcare professionals by members of the medical department of the MAH.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Following the ECJ's decision in the *Ludwigs* case (Case C-143/06), the Medicinal Products (Control of Placing on the Market) Regulations 2007 were amended to provide that where products are made available pursuant to the compassionate use exemption, "no advertisement relating to the product, other than one that states only the trade name, pack size, price and dose" may be issued at the request or with the consent of the pharmacist, wholesaler or manufacturer, and the regulations are clear that no such advertisement or representation may be issued with a view to it being seen by the general public. As a consequence, authorised manufacturers are now permitted to provide pharmacists and wholesalers with information in respect of the trade name, pack size, price and dose quantity for such exempt medicinal products. Previously, an authorised manufacturer was prohibited from issuing any advertisement in respect of such products, whether by means of any catalogue, price list or circular.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

The Pharmaceutical Code does not specifically exclude such information from the definition of promotion. The provision of such information in the absence of a specific request by the institution is likely to be deemed promotional, and therefore subject to the prohibition on the promotion of unapproved products.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Under the Pharmaceutical Code, market research is permitted but cannot be used as a form of disguised promotion, including promotion of unauthorised medicinal products or unauthorised therapeutic indications of authorised products. Accordingly, market research activities that may be deemed as disguised advertising would be prohibited on the basis of unapproved medicinal product promotion. Certain guidance can be found in the Pharmaceutical Code, which states that methods used for market research must never discredit or reduce confidence in the industry. Research questions must not be phrased in order to solicit disparaging references to competitors or their products. Access to participants must not be gained by subterfuge and only minimal incentives can be given, which must be commensurate with the work involved. While there is no specific national guidance on market research in Ireland, the European Pharmaceutical Market Research Association (the "EphMRA") has published a Code of Conduct which provides guidance in this area.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The Regulations require certain minimum information to be provided to healthcare professionals, including the product's name, a list of active ingredients using the common name placed immediately adjacent to the most prominent display of the product name, the classification for the sale or supply of the product, one or more of the product's indications and the method of administration where it is not obvious. A clear and legible statement of the information in the SmPC regarding adverse reactions, precautions and contraindications, dosage and method of use relevant to the indications must be positioned within the advertisement so as to enable the reader to readily appreciate the relationship between this information and the claims and indications of the product. The name and address of the holder of the marketing authorisation, certification of registration or certificate of traditional use registration or the business name and address of the part of the business responsible for placing the medicinal product on the market, should also be provided along with the authorisation number. If applicable, the words "traditional herbal medicinal product for use in", followed by one or more therapeutic approved indications, and followed by the words "exclusively based upon long-standing use", should be included. Separate requirements exist for abbreviated reminder advertisements. The Pharmaceutical Code adds that this information should be clear, legible and an integral part of the promotional material.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

In advertising to persons qualified to prescribe or supply, such an advertisement must contain the information set out in question 3.1 above. The Pharmaceutical Code prohibits the making of exaggerated

claims in advertising, as well as making disparaging references to other producers' products, services or promotions. The use of a rival producer's logos or brands is prohibited unless their consent has been received. It is prohibited to advertise a product as being "new" if it has been generally available in Ireland for more than 12 months. It is also prohibited under the Pharmaceutical Code to use the word "safe" in an advertisement without qualification. Comparisons with rival products must be factual, fair and capable of substantiation. The Regulations are silent on the specific point of referring to studies which are not in the SmPC, except to say that information may not be included if it is not accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the product. The Pharmaceutical Code requires all promotional information to be consistent with the information in the SmPC. MAHs must therefore ensure that all information concerning studies not included in the SmPC is consistent with, and does not contradict the information in the SmPC. It is also prohibited to include in written advertising any quotation, tables or other illustrative matter taken from a medical journal or other scientific work unless it is accurately reproduced and the precise sources of the information are indicated.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Names and photographs of healthcare professionals must not be used without their consent, or in a manner that would breach the ethical code of the appropriate profession. Testimonials do not constitute substantiation and the opinions expressed should be supported with independent evidence of their accuracy. Clinical and/or scientific opinions of healthcare professionals cannot be directly or implicitly disparaged. Quotations from medical literature or personal communications received from healthcare professionals must accurately reflect the meaning of the author and the significance of the study. The ASAI Code requires all endorsements for medicinal products that give the impression of professional advice, and all recommendations, to come from persons who are suitably qualified and have relevant and recognised qualifications.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Both the Regulations and Pharmaceutical Code are mute on comparative claims in respect of "head to head" clinical trials. Nevertheless, the Pharmaceutical Code requires comparisons of medicinal products to be factual, fair and capable of substantiation. Comparisons must not mislead by distortion, undue emphasis, omission or in any other way. In addition, the Misleading Advertising Regulations require claims to objectively compare one or more material, relevant, verifiable, and representative features of products.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

From a general perspective, comparative advertising is permitted under the Trade Marks Act, 1996, provided it is in accordance with honest practices in industrial or commercial matters and does not take unfair advantage of, or is not detrimental to, the distinctive character or reputation of the trademark. Such advertising must also comply with Misleading Advertising Regulations and the CPA, which prohibits misleading comparative advertising. Under the Pharmaceutical Code, however, brand names cannot be used in comparator advertisements without the prior consent of the relevant brand owner. In addition, the products, services and promotions of other companies cannot be disparaged in advertising either directly or implicitly. Due to the prohibition on the promotion of unauthorised medicinal products, unauthorised competitor products should not be referenced in promotional material. See also question 3.3 above.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The Pharmaceutical Code specifically states that its application is not intended to inhibit the exchange of medical and scientific information during the development of a preparation. The distribution of scientific papers at international congresses or symposia held in Ireland is permissible. There are, however, certain requirements to be met before distributing such papers. See also question 2.1.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Neither the Regulations, nor the Pharmaceutical Code, deal specifically with "teaser" advertisements. Nonetheless, the applicable provisions of the Regulations and Pharmaceutical Code must be observed at all times in respect of the promotion of medicinal products.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

In the above scenario, the MAH for Product B would not be permitted to promote such combination use based on the approved SmPC for Product A. The MAH for Product B would be required to vary the SmPC for Product B before promoting combination use. Article 11 (4.5) of the Directive, as implemented in Ireland by the Regulations, expressly provides that the "interaction with other medicinal products and other forms of interactions" must be noted on the SmPC.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

The Regulations prescribe requirements in relation to the distribution of samples. Free samples of medicinal products may only be supplied to persons who are qualified to prescribe such products, on an exceptional basis only and for the purpose of acquiring experience in dealing with the product. When distributed by medical representatives, they must be handed directly to the individual qualified to prescribe, or his agent. Samples may only be provided in response to a written request (signed and dated). A maximum of six samples, per year, per recipient, may be provided and only in the smallest presentation of the product on the market, marked "Free Medical Sample – Not for Sale".

Under the Pharmaceutical Code, sampling shall not extend beyond two years after the samples were first requested for each particular new medicinal product. Additional strengths or different dosages cannot be considered as new medicinal products. Each sample must be accompanied by the most up-to-date SmPC and, if sent by post, adequately packaged to be reasonably secure from the access of children. Free samples of anti-depressants, hypnotics, sedatives or tranquilisers are prohibited, along with any controlled drug as defined in section 2 of the Misuse of Drugs Act 1977, as amended. The Regulations also require the supplier of samples to maintain an adequate system of control and accountability.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

It is prohibited to supply, offer or promise gifts, pecuniary advantages or benefits in kind to healthcare professionals ("HCPs"), in the course of promoting medicinal products. Healthcare professionals are also prohibited from accepting such items. From 1 July 2014, the limited exemptions that were previously in place have been abolished and a blanket prohibition on gifts comes into force. The prohibition does not apply to the transmission of information or educational materials or to items of medical utility which will be permitted in certain circumstances. The transmission of information or educational materials will be permitted, provided they are: i) inexpensive; ii) directly relevant to the practice of medicine or pharmacy; and iii) directly beneficial to the care of patients. Companies may provide items such as pens and paper pads exclusively during company organised meetings, as long as they are non-product branded and inexpensive. Items of medical utility aimed directly at the education of healthcare professionals and patient care may be provided if they are inexpensive and do not offset the cost of routine business practice of the recipient. These are not considered gifts.

In addition, section 15 of the Ethics in Public Office Act, 1995, as amended, imposes a disclosure obligation on the recipient of a gift for any gift given to a HCP employed by the State or their spouse, civil partner or child, which exceeds a monetary value of €625.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

A pharmaceutical company may provide support in the form of Healthcare Support Services ("HSSs"), educational, research or employment grants and the donation or sponsorship of medical equipment for the betterment of patients. Such support must be in response to a written request from the healthcare organisation or healthcare professional for a specific type of support that must be genuinely needed. While healthcare professionals may request the support provided, support must be paid directly to the relevant healthcare organisation only and the support provided must be relevant to the practice of medicine or pharmacy and be intended for use solely in the organisation. The provision of any such support must not be conditional on the prescription, supply or use of the company's products or be linked in any way to promotion. The support must be modest, reasonable and in proportion to the scale and scope of the recipient institution. The Pharmaceutical Code also obliges companies to make publicly available information in relation to these donations, grants and sponsorship and from 1 January 2016, companies will be required to make public details of all "Transfers of Value" that occurred in 2015. There are no monetary limits for these forms of support. Companies should actively check that their support has been spent as intended and the written agreement must require that the support has been spent as agreed.

HSSs are defined as process enhancement initiatives or medical service supports (e.g. patient compliance initiatives, sharps bin services, etc.) provided by a pharmaceutical company that ultimately improves patient care and welfare. A HSS must have the objectives of monitoring disease activity, achieving better healthcare outcomes and enhancing patient care. They must be non-promotional, must not be designed as an inducement to prescribe and must not be designed or operated in a promotional manner. The operation of the HSS must be monitored with reference to its objectives. A HSS may be provided directly or indirectly to patients. Contractual arrangements with service providers should clearly outline the service, the requirements for safety reporting, adherence to data privacy requirements, etc. Information collected in the provision of a HSS may not be used for promotional purposes and may not be used for clinical research purposes without the appropriate prior written consent of the healthcare provider and the patient.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

As per question 4.2 above, as of 1 July 2014, a blanket prohibition on gifts comes into effect. However, this prohibition does not apply to the transmission of information or educational materials or to items of medical utility which will be permitted in certain circumstances.

However, the provision of such information or items must not be directly or indirectly intended to change prescribing habits and increase market share for such products. The Pharmaceutical Code also prohibits the provision of support where it is linked in any way to direct or indirect product promotion.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

The negotiation of price margins and discounts is allowed in the ordinary course of business. Any discounts must be clearly set out in the sales invoice.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

The Regulations do not allow "inducements" for the purposes of increasing sales of particular products. This example is likely to be considered an inducement and so would be contrary to the Regulations.

The Regulations allow for the negotiation of prices, margins and discounts in the ordinary course of business provided that such prices, margins and discounts are incorporated in the sales invoice as a consequence of such negotiation. Package deals linked to product purchases as such are not recognised in the Pharmaceutical Code. With reference to HSSs, no commitment must be sought or given in relation to the prescribing, supply or use of the company's products.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

The Consumer Code prohibits offering a refund to a dissatisfied customer. The ASAI Code also provides that any marketing material for pharmaceutical products shall not offer refunds in similar situations. These rules do not distinguish between prescription-only medicinal products or over-the-counter products.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

See question 4.3 above. Sponsorship of continuing medical education is permitted provided it is related to *bona fide* continuing education. Any support or financial assistance given must be "unrestricted", which means that the content must be developed independently of the pharmaceutical company's influence and not adversely affect the judgment of a medical practitioner.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Under the Regulations, a person shall not, in the course of promoting medicinal products to persons qualified to prescribe or supply such products, supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy. The guide to professional conduct and ethics for registered medical practitioners published by the Irish Medical Council also governs this area and notes that doctors have a responsibility to make sure their work is not influenced in any way as a result of sponsorship or any other relationship with a pharmaceutical, medical device or other commercial company. There is also general anti-bribery legislation which applies to the life sciences industry. The Ethics Acts apply to promotional practices involving healthcare professionals who also hold certain designated public positions or directorships.

The 2018 Act also applies in circumstances where promotional practices are found to be corrupt. Section 6 of the Act states that it is an offence for any person alone, or in conjunction with others, to corruptly give, promise, offer, request, accept or obtain any gift, consideration or advantage as an inducement to, or reward for, or otherwise on account of an official in relation to the office, employment, position or business. The definition of "official" includes an officer, director, employee or member of an Irish public body. A gift can take the form of money or property. Public bodies in Ireland include the HSE, which covers all publicly run hospitals within the state. Public bodies can also include any other body, organisation or group that is financed wholly or partly out of monies provided by the Irish government. As such, semi-private or private hospitals may also fall within the scope of the Act if those hospitals receive funding from the state.

In practice there have, to our knowledge, been no enforcement cases in the area of compliance with anti-bribery/anti-corruption legislation in the pharmaceutical sector. Most of the enforcement cases to date specifically deal with property planning issues in Ireland.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Hospitality is permitted provided that the assistance provided is:

- related to *bona fide* continuing education and is objectively reasonable;

- secondary to the main purpose of the event taking place;
- does not exceed the level that recipients would normally pay for themselves;
- is not extended to spouses or other accompanying persons who would not qualify in their own right; and
- does not include sponsoring, securing and/or organising, directly or indirectly, any entertainment, sporting or leisure events.

Support for smaller local clinical meetings must be in response to a formal written request, indicating the exact anticipated items of expenditure, and support must only be given for room hire, equipment hire, actual travel expenses of speakers, honorarium to speakers and/or modest meals and light refreshments. No one company should sponsor a series of such meetings. Sponsorship of larger meetings is permitted, but should not be undertaken by any one company to the exclusion of other available and willing sponsors. Unless there is a valid reason to do so, a pharmaceutical company may not organise an event that is to take place outside Ireland. A valid reason exists if the majority of the invitees are based abroad, or if the relevant resource or expertise is based abroad. Where the hospitality occurs in another Member State bound by the European Federation of Pharmaceutical Industries and Associations ("EFPIA") HCP and Disclosure Codes, the hospitality threshold set in that Member State will apply. In such circumstances, approval of the hospitality thresholds should be made by the company affiliate where the hospitality takes place. However, the Pharmaceutical Code provides that hospitality arrangements offered to Irish healthcare professionals abroad must also meet the general obligations in the Pharmaceutical Code. In such circumstances, approval of the hospitality arrangements (other than the hospitality thresholds) must be undertaken by both the affiliate in Ireland and the affiliate in the Member State in which the hospitality takes place. It is the programme that must attract the attendees and not the venue or the hospitality. International events should not coincide with major sporting events. Hospitality may be offered at sales promotion or other events for purely professional and scientific purposes, provided it is reasonable in level, strictly limited to the main purpose or scientific object of the event and is not extended to other persons. Where pharmaceutical companies provide or offer meals to healthcare professionals, the value of each meal (including food and beverages) may not exceed the monetary threshold set by the Pharmaceutical Code, currently €80 per recipient. This threshold includes VAT but excludes any gratuity, and only applies to events held in Ireland. Hospitality occurring in another Member State may be bound by the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, if the company is a member of the EFPIA or the national industry association affiliated with the EFPIA. In such circumstances, the company must comply with the hospitality threshold set in that Member State.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

It is not possible to compensate a healthcare professional for attending or for his or her time travelling to such a meeting. Depending on the time, location and length of the meeting, travel expenses, meals, refreshments, accommodation and registration fees may be covered.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

This is not specifically dealt with in the Pharmaceutical Code, but pharmaceutical companies are generally held responsible for the contents of, and the hospitality arrangements for, scientific meetings directly sponsored or organised by the company. Pharmaceutical companies that provide sponsorship to individual healthcare professionals to attend independent meetings must ensure that the meeting content does not discuss the company's unauthorised medicinal products or unauthorised therapeutic indications of the company's products, as the authorities could consider this to be an unauthorised promotion of the company's products. Responsibility in relation to the hospitality arrangements will depend on the level of sponsorship provided by the pharmaceutical company. However, authorities could take the view that companies must ensure that any hospitality offered to those sponsored healthcare professionals meet the local requirements as otherwise this could be considered an unauthorised advantage or benefit to the healthcare professional from the company itself.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Healthcare professionals are permitted to partake in market research, medical/scientific studies and clinical trials. The Pharmaceutical Code states that they are entitled to be remunerated for their time as long as there was a legitimate need for the services, a written contract is signed in advance, specific criteria applied to the selection of the doctor, a reasonable number of doctors are retained, records of services are maintained, the engagement is not an inducement to prescribe and the compensation is reasonable and reflects the fair market value of the services provided. There are no specific rules on advisory boards. Advisory boards are, however, generally constituted to obtain in-depth insight, input, reactions, feedback and information from advisors in order to answer specific questions that could not be otherwise determined in the absence of the conduct of the advisory board. Advisory boards should never be used as a means to promote approved or investigational products or off-label indications of approved medicinal products. The agenda should demonstrate that the time spent providing information by the company organising the advisory board is subordinate to the time spent gathering information from the advisors. Consultants are encouraged to disclose their relationships with companies when they write or speak in public.

From 1 January 2016, companies will be required to make public details of all Transfers of Value that occurred from 1 January 2015. Disclosures must be made on an annual basis and each reporting period covers a full calendar year. The Pharmaceutical Code allows for disclosure by way of either: (i) the company's website; or (ii) a central platform. A further point to note in relation to consultants is that Transfers of Value relating to expenses agreed in the written agreement covering their activity will be disclosed as two separate amounts.

### 5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

Post-marketing surveillance studies must not be promotional or used as a means to induce a healthcare professional to prescribe, etc., and must be conducted with the main objective of developing science or education. Incentives given must be kept to a minimum and be commensurate with the work involved. Non-interventional studies must be conducted with a scientific purpose, according to a written study plan and in accordance with a written agreement, and any remuneration must be reasonable and reflect the fair market value of the work performed. The study should be approved by the company's scientific service and the results should be analysed, summarised and distributed in accordance with company procedures, and records retained.

### 5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

See question 5.4 above. Payment is possible in circumstances where the remuneration is reasonable and reflects the fair market value of the services provided. Access to respondents must not be gained by subterfuge and incentives should be kept to a minimum. Questions which would disparage competitors are to be avoided. Market research should not be disguised as sale promotion. As such, companies would be advised to perform blinded market research using a third-party market research provider who would be responsible for paying the healthcare professionals.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Advertising of non-prescription medicinal products to the general public is permitted subject to the requirements of the Regulations, the Consumer Code and the ASAI Code. Before a medicinal product can be advertised, it must be the subject of a marketing authorisation or a certification of traditional use (in respect of herbal medicinal products). Such an advertisement must be accurate, must present the product objectively and be consistent with the terms of the marketing authorisation and the SmPC of the product, and must encourage rational use of the product. It must not contain material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary by offering treatment or diagnosis remotely;

(b) suggests that the effects of the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or product;

(c) suggests that the health of the subject can be enhanced by taking the medicinal product;

(d) suggests that the health of the subject could be affected by not taking the medicine (this prohibition shall not apply to vaccination campaigns provided that such campaigns have been approved by the minister);

(e) is directed exclusively or principally at children;

(f) might result in harm to children or which exploits their credulity;

(g) leads the public to assume that the medicinal product has some special property or quality which is in fact unknown or unrecognised;

(h) claims that the product, medicine or treatment advertised will promote sexual virility or be effective in treating sexual weakness (unless it is authorised for such an indication) or habits associated with sexual excess or indulgence or any ailment, illness or disease associated with those habits;

(i) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity status could encourage the consumption of medicinal products;

(j) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

(k) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(l) could, by giving a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(m) refers, in improper, alarming or misleading terms, to claims of recovery; and

(n) uses in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

The Regulations contain requirements as to the form and content of advertisements in that the product must be clearly identified as a medicinal product and include certain minimum information, such as the name of the product and instructions for use. The Consumer Code outlines further requirements, including that advertisements:

- must be accurate, truthful and easily intelligible;
- should not bring the industry into disrepute or prejudice public confidence in medicinal products;
- should not offer treatment for a serious disease requiring intervention by a healthcare professional;
- should not refer to chronic conditions or should not offer to treat by correspondence, denigrate or unfairly attack other products; and
- should not use testimonials in an advertisement except where they are limited to the genuine views of the user and an official or certified copy is available with a signed and dated release of the person giving it.

Testimonials shall not be used in an advertisement for more than three years after the date on which they were produced by the users and shall not contain anything contrary to the provisions of the Code of Standards. Certain non-prescription medicinal products should not be promoted to the public, such as analgesics containing codeine, and special requirements apply when advertising antihistamines and/or sympathomimetics. The general provisions of the CPA regarding misleading commercial practices and prohibited commercial practices apply, prohibiting, for example, a representation that a product is able to cure an illness, dysfunction or malformation, if it cannot. The Pharmaceutical Code also prohibits the making of exaggerated claims in advertising, as well as making disparaging references to other producers' products, services or promotions. The use of a rival producer's logos or brands is prohibited unless their consent has been received. It is prohibited to advertise a product as being "new" if it has been generally available in Ireland for more than 12 months. It is also prohibited to use the word "safe" in an advertisement without qualification. Comparisons with rival products must be factual, fair and capable of substantiation and meet the requirements of the Misleading Advertising Regulations.

The ASAI Code also includes specific provisions in relation to the advertisement of medical products, including medicinal products. Those provisions largely reflect the requirements provided in the Regulations, the Pharmaceutical Code and the Consumer Code.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

The Regulations prohibit the advertisement of prescription-only medicinal products or controlled drugs which are "directed wholly or mainly at members of the general public". This does not apply to the promotion of a vaccination campaign in respect of a vaccine or serum, provided the campaign is approved by the Minister. The BAI Code prohibits commercial communications specifically concerned with products available only on prescription.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are permitted to the extent that they do not in any way promote a brand of medicinal product, either directly by naming a product, or indirectly, for example:

- If there are non-prescription, as well as prescription-only, medicinal products available to treat a particular condition, advising patients to visit their doctor for treatment could be regarded as promoting the use of a prescription-only medicinal product. To avoid any such inference, the Pharmaceutical Code advises that consideration should be given to advising patients to talk to their doctor or pharmacist.
- In the case of a disease awareness campaign sponsored by a company which promotes the only available medicinal product for that disease/condition, particular care is required to ensure that the campaign could not be regarded as promoting that product. The Pharmaceutical Code notes that statements such as "your doctor can prescribe a medicinal product to help you" should be avoided.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

While not explicitly classified as "advertising" in the Regulations, press releases are expressly included in the definition of "promotion" in the Pharmaceutical Code. The Pharmaceutical Code prohibits the advertising or promotion of prescription-only medicinal products to the general public. Information about a scientific discovery of a medicinal product, however, may be supplied where it is desirable or necessary to do so in the public interest or where the object is to keep the public informed of scientific or medical progress. Information must be presented in a balanced way to avoid the risk of raising unfounded hopes in the public mind from the results of treatment. Statements must not be made to or designed for the purpose of encouraging members of the public to ask their doctor to prescribe a medicinal product. Therefore, such press releases must include only factual and non-promotional information.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

The Pharmaceutical Code recognises that information about scientific discoveries and research initiatives may need to be disclosed to shareholders or others in the context of corporate brochures and Annual Reports. Care must be taken to ensure that such information complies with the requirements of the Regulations and Pharmaceutical Code governing the promotion of medicinal products.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Annex III of the Pharmaceutical Code contains guidelines for pharmaceutical companies on working with patient organisations. Pharmaceutical companies must ensure that the independence of patient organisations is respected and guaranteed. Medicinal products must not be directly or indirectly promoted through these groups.

It is permissible for a pharmaceutical company to donate to a patient organisation either for general purposes, for a particular project or piece of research, by sponsoring speakers for events or for undertaking projects of joint interest. Each company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support, including the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the description must describe clearly the non-monetary benefit that the patient association receives. This information may be provided on a national or European level and should be updated at least annually.

A pharmaceutical company may contract services from patient organisations, but only where such services are provided for the purpose of supporting healthcare or research. A written contract is required, which should include certain specified provisions, including a provision obliging the patient organisation to declare that it has provided paid services to the company whenever it writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company, and a provision confirming that the extent of the service should not be greater than is reasonably necessary. The compensation must be reasonable and not exceed the fair market value of services provided. A company must make publicly available a list of patient organisations that it has engaged to provide significant contracted services and the total amount paid per patient organisation over the reporting period. No one company should fund a patient organisation to the exclusion of other available and willing sponsors, except by the choice of the patient organisation, which is free to exercise its independence in determining who it wants to work with. Any hospitality provided by a pharmaceutical company to patient organisations, and their members, should be reasonable, and secondary, to the main purpose of the event for which it is provided, and must not involve sponsoring or organising entertainment. Hospitality may only be extended to persons who qualify as participants in their own right, but in exceptional cases, may be provided to a *bona fide* "carer" of a participant in the case of clear health needs.

Finally, pharmaceutical companies should not offer free samples to patient organisations.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Companies are permitted to provide information, educational materials or items of medical utility to healthcare professionals for the benefit of patients in certain circumstances. The transmission of information or educational materials will be permitted, provided

they are: i) inexpensive; ii) directly relevant to the practice of medicine or pharmacy; and iii) directly beneficial to the care of patients. Companies may provide items such as pens and paper pads exclusively during company organised meetings, as long as they are non-product branded and inexpensive. Items of medical utility aimed directly at the education of healthcare professionals and patient care may be provided if they are inexpensive and do not offset the cost of routine business practice of the recipient. These are not considered gifts. Healthcare professionals may be provided with items which are to be passed on to patients which may bear the name of a medicinal product and/or information about medicinal products only if such detail is relevant to the appropriate use of the medicinal product by patients who have been prescribed that product. Additionally, although items which are to be passed on to patients may not be issued at healthcare professional exhibition stands, they may be exhibited and demonstrated on healthcare professional stands and requests for them can be accepted for later delivery. Patient support items may be provided to healthcare professionals by medical representatives during the course of a promotional call and medical representatives may deliver such items when requested by a healthcare professional. Companies may not provide free samples of products directly to patients. While there are no rules on the direct provision of items to patients, such activities could be considered as prohibited indirect promotion of a company's medicinal product if the activities relate to prescription-only products.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Other than submitting relevant information to the various regulatory authorities, there is no requirement, legislative or otherwise, to publicly disclose details of ongoing or completed clinical trials.

However, when the new Clinical Trials Regulation (Regulation EU No 536/2014) becomes applicable in Ireland and other EU Member States, pharmaceutical companies will be required to make available to the public certain data concerning clinical trials conducted in the EU in which the company is a sponsor. While pharmaceutical companies are not currently required to publicly disclose synopses of clinical study reports, the new Clinical Trials Regulation will, from the date of its entry into force, require the public disclosure of clinical study reports on a publicly accessible database. Patients must also be given access to the summary of the results of the clinical trial presented in terms understandable to the patient. Sponsors of clinical trials may be able to prevent disclosure of certain data on the basis that such data represents commercially confidential information or breaches the applicable data protection requirements.

Pharmaceutical companies and trade associations in the EU are increasingly adopting voluntary commitments concerning the disclosure of clinical trials. Such voluntary commitments include the Joint Principles adopted by EFPIA and Pharmaceutical Research and Manufacturers of America ("PhRMA"). As part of the initiative for greater transparency and better access to clinical trial information, companies register ongoing clinical trials and results of completed clinical trials on the IFPMA Clinical Trial Portal and for many of the larger companies with larger websites, on their company websites.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no requirement in legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The requirements for companies to make publicly available information about transfers of value is set out in the self-regulatory Pharmaceutical Code and are applicable only to members of the IPHA or EFPIA. Pharmaceutical companies are required to disclose transfers of value made by them, whether directly or indirectly. This obligation does not extend to transfers of value that: (i) are solely related to over-the-counter medicinal products; (ii) are not listed in Article 3 of Annex V of the Pharmaceutical Code, including items of medical utility, meals and drinks, samples; or (iii) are part of the ordinary course of purchases and sales of medical products by and between a pharmaceutical company and a healthcare professional or healthcare organisation. Disclosures must be made from 1 January 2016 on an annual basis and each reporting period covers a full calendar year. The Pharmaceutical Code allows for disclosure by way of either (i) the company's website, or (ii) a central platform. The first reporting period will be from 1 January 2015 and the information will be made public no later than 1 July 2016. Disclosures must be made by pharmaceutical companies within six months after the end of the relevant reporting period, and the information disclosed must remain in the public domain for a minimum of three years after the time such information is first disclosed, unless the recipient's consent relating to a specific disclosure has been revoked. Disclosures must be made pursuant to the national code of the country where the recipient has its physical address. Pharmaceutical companies must document all transfers of value required to be disclosed and maintain the relevant records of the disclosures for a minimum of five years after the end of the relevant reporting period.

Except as expressly provided by the Pharmaceutical Code, transfers of value shall be disclosed on an individual basis. Pharmaceutical companies must disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to the transfers of value to such recipient in each reporting period which can be reasonably allocated to one of the following categories:

- In relation to transfers of value to a healthcare organisation, disclosure requirements are in respect of amounts related to: i) donations and grants; ii) contribution to costs related to events; or iii) fees for service and consultancy.

- In relation to transfers of value to a healthcare professional, disclosure requirements are in respect of amounts related to: i) contribution to costs related to events; or ii) fees for service and consultancy.

Where a transfer of value, which would otherwise reasonably be allocated to one of the above categories, cannot be disclosed on an individual basis for valid legal reasons, a pharmaceutical company must disclose the amounts attributable to such transfers in each reporting period on an aggregate basis. A template form in respect of the disclosure of Transfers of Value has been included in section 5 of the Pharmaceutical Code. This form should be used for disclosures so as to ensure consistency and that the requirements of the Pharmaceutical Code are met. The Pharmaceutical Code implements the EFPIA Disclosure Code without variation.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

If a healthcare professional does not agree to the individual disclosure of details related to transfers of value provided to the individual in question, pharmaceutical companies are required to refrain from disclosing such information. In such circumstances, pharmaceutical companies can disclose the information in aggregate format so as not to identify the individual healthcare professional. The company is also required to indicate the number of healthcare professionals included in the aggregate disclosure in the total number of healthcare professionals disclosed.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

The scope of the Regulations extends to advertising on the internet, and the Pharmaceutical Code specifically includes the use of the internet as a means of promoting pharmaceutical products. Only non-prescription medicinal products can be advertised to the public through the internet, subject to certain restrictions, which are the same as those outlined above in question 6.1. Prescription medicinal products can be advertised through the internet to persons qualified to prescribe or supply them, but only with his or her prior consent to receive targeted marking communications. Pharmaceutical companies should also be careful not to target online advertising to other countries where the relevant product does not have a marketing authorisation. Annex IV of the Pharmaceutical Code provides detailed requirements in relation to Digital Communication in the Pharmaceutical Sector.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Restricted information should only be placed in a secure part of a website for registered users or subscribers only. A prominent disclaimer should be included on the website requiring users to confirm their status as a healthcare professional prior to accessing the full site and a hyperlink to an alternative website appropriate for the general public should also be included.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Pharmaceutical companies should be aware that linking and reverse linking to sites may not always be permissible, as it may raise copyright issues or breach the Acceptable Use Policy of the relevant website. It is therefore prudent to seek the consent of the relevant website owner in advance. A pharmaceutical company should include a disclaimer on its website to the effect that it has no control over and disclaims all liability for the accuracy of the content of the linked website, that it is not affiliated in any way with the site and that draws the user's attention to any Acceptable Use Policy or Terms and Conditions of the linked site. It should be clear to the platform visitor whether the link is to a company sponsored site or an independent site. Users should be given a clear indication when they are leaving digital platforms owned or funded by a company to be directed to an external platform.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

As the definition of advertising is very broad (see question 1.2 above), a pharmaceutical company should ensure that all information contained in a website complies with the requirements of the Regulations and with the Codes, paying particular attention to the differing rules applicable to prescription-only and non-prescription medicinal products and their promotion to patients.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The general rules relating to the advertising of medicinal products apply to the use of the internet and/or social media. Only non-prescription medicinal products can be advertised to the public, and this includes marketing that is conducted online or by post, telephone, e-mail or other electronic communications. The advertisement must not give the impression that a medical consultation or surgical operation is unnecessary, particularly by offering a diagnosis or by suggesting treatment remotely. Prescription medicinal products can be advertised through the internet, but only to individuals qualified to prescribe or supply them, and only with the individual's prior consent. Restricted information should only be placed in a secure part of a website for registered users or subscribers only.

The Pharmaceutical Code includes Annex IV on Guidance on Digital Communication in the Pharmaceutical Sector. Annex IV advises that pharmaceutical companies should have a clear policy in place regarding social media use by company employees. It states that providing responses to inquiries received from healthcare professionals through digital channels is acceptable if performed in accordance with the Pharmaceutical Code. The use of electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient. The responsibility rests with the company to ensure that receipt of the response is restricted to the healthcare professional making the inquiry or their nominee. It may be acceptable to contact patients through social media channels in certain circumstances (e.g. reminding them to regularly take their prescribed medication) if documented approval from both the healthcare professional and the patient is received and, in the example given, the message carries no

purpose other than supporting patient compliance with the medication schedule instructed by the patient's healthcare professional.

Annex IV advises that it is a question of policy for a pharmaceutical company as to whether it is appropriate to correct erroneous entries on non-company mediated sites but cautions that care needs to be exercised since, if a company corrects certain information but omits to correct other information that may be perceived as related, such behaviour may be interpreted as a breach of the Pharmaceutical Code.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The 7th edition of the ASAI Code includes a new section on advertising rules for health products. The rules are largely based on the provisions of the existing Regulations and the Pharmaceutical Code.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

We are not aware of any significant developments in the next year.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The HPRA is increasingly active and is pursuing more cases arising out of breaches of the Regulations each year. The HPRA has been increasingly monitoring advertising practices through social media.

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ARTHUR COX

Arthur Cox is one of Ireland's leading law firms, with over 500 legal staff and almost 100 partners. An 'all-island' firm with offices in Dublin and Belfast, it also has offices in London, New York and Silicon Valley. The firm is a market leader in the provision of legal services to the life sciences industry, with a multi-disciplinary practice group successfully combining corporate, commercial, transactional, regulatory, product liability, competition and intellectual property expertise to serve domestic and international clients in the pharmaceutical, biotechnology, medical devices, food and cosmetics industries in Ireland. The Life Sciences team advises on all aspects and stages of the life cycle of products, from research and development through to manufacturing and marketing. It has extensive experience in the sector and strong links with local and EU trade and regulatory associations, and counts many of the world's leading pharmaceutical, medical device, biotech and agribusiness companies among its clients.

# Israel

Liad Whatstein

Uri Fruchtman

Liad Whatstein & Co.

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The laws and codes of practice that govern the advertising of medicinal products in Israel are: the Pharmacists' Regulations (Preparations), 1986 ("the Preparations Regulations"); the Pharmacists' Regulations (sale of a product not in a pharmacy or not by a pharmacist), 2004 ("GSL Regulations"); MOH Procedures; the Rules of the Second Authority for Television and Radio (Ethics in TV Commercials), 1994; the Rules of the Second Authority for Television and Radio (Ethics in Radio Commercials), 1999; and the Joint Ethical Convention between the Israeli Medical Association (IMA) and Pharma Israel (the representative organisation of the innovative pharmaceutical companies in Israel), 2014.

### 1.2 How is "advertising" defined?

"Advertising" is defined as "the provision of information in writing, via the media or in any other form" (the Preparations Regulations, section 1). In addition, with respect to general-sales-list (GSL) medicines, advertising is defined as "publication, orally uttered, in writing, in print or by other means of communication, made by an interested party with respect to the marketing of a [GSL] non-prescription medicinal product or made on its behalf and which is directed to the public at large or to a section of the public" (the GSL Regulations, section 1).

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no mandatory arrangements under Israeli legislation to ensure compliance by companies with the various laws and codes of practice on advertising. However, under the Joint Ethical Convention between the IMA and Pharma Israel, as updated in 2014, pharmaceutical companies are guided not to disseminate promotional materials without approval from the "relevant professional body in the company", "that possesses appropriate scientific background and professional skills" (section 94). In addition, pharmaceutical companies are guided to "consolidate and uphold procedures that would guarantee full implementation" of (among others) the above guidance (section 97).

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no legal or code requirements in Israel for companies to have SOPs governing advertising activities, other than the general guidance for companies under the Joint Ethical Convention to maintain an internal approval mechanism, as detailed in our answer to question 1.3. With respect to the requirements for companies to employ personnel with a specific role and the requirements regarding such specific personnel, see the answer to question 1.3.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Any advertising of medicinal products must be approved in advance by the Israeli Ministry of Health (MOH). Under MOH Procedure No. 24 (as updated in 2005), an application for approval must be filed with the MOH Pharmaceutical Division on an appropriate form, together with the suggested advertisement and the product's approved Patient Package Insert (leaflet), as further detailed in the Procedure. Under the Procedure, the MOH will handle an application for approval within 21 working days and strive to examine each application within 10 working days. In the event that the MOH informs the company that changes need to be made to the advertisement and the company submits an amended advertisement, the MOH will examine the amended advertisement within 14 working days. The period of validity of any advertisement approval is one year only but is extendable at the discretion of the MOH. In addition, any TV/radio advertisement of medicinal products must be approved in advance by the Israeli broadcast authorities.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Under MOH Procedure No. 24 and the GSL Regulations, if the Director General of the MOH determines that an advertisement

which has been issued is in breach of the Regulations, he may cancel the approval for the advertisement (thereby stopping the further publication of that advertisement) or obligate the owner of the advertisement to publish an amended advertisement (in the same language and the same media medium in which it was originally published) or to publish a "clarification, approved by the Director General, indicating that the advertisement is misleading and inaccurate" (in at least three daily newspapers and as further detailed in the procedure and Regulations). In accordance with the general principles of Israeli administrative law, any decision by the Director General may be appealed to the competent court.

In addition, if an inquiring committee set under the Joint Ethical Convention between the IMA and Pharma Israel, as updated in 2014, determines that a Convention rule has been violated by a pharmaceutical company or any one acting on its behalf, it is empowered to order the company to take any action that is required to remedy the violation (section G.1 of the Convention). However, such inquiring committee may be formed only following a complaint (which may be filed by any person). In addition, the Convention focuses (with respect to advertising) on advertising by physicians or through promotional materials which are normally disseminated to physicians rather than to the general public, and is likely not to intend to cover advertising to the general public.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Previously, any violation of any of the rules governing the advertising of medicines, in as much as they were set in either the general Preparations Regulations or the specific GSL Regulations, were subject to a criminal sanction of six months imprisonment. Following an amendment in 2016 to the Pharmacists Ordinance, 1981 (the primary legislation under which both Regulations were promulgated), currently, only a violation of some of the advertising rules set in the GSL Regulations remains subject to the criminal sanction of six months imprisonment, while violation of advertising rules set in the Preparations Regulations is no longer subject to any criminal sanction. However, following the said amendment, violation of the advertising rules under the Preparations Regulations is now subject to a MOH regulatory fine in an amount of up to NIS 150,000 (approximately USD 42,000), and if the infringer is a corporation – in an amount of up to NIS 300,000 (approximately USD 84,000).

Traditionally, the Israeli MOH (which is responsible for enforcing the advertising rules) was satisfied with instructing companies to take off unlawful advertisements or make changes to advertisements to remedy violations of the advertising rules. To date, there are no reported instances of any action (criminal prosecution or imposition of regulatory fines) taken against companies.

The rules relating to advertising do not create a specific mechanism enabling competitors to take direct action through the courts in relation to advertising infringements. However, it is assumed that competitors may likely take direct legal action against the advertiser under a number of legal doctrines and causes of action.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The only self-regulatory process in Israel which may be applicable to violations of advertising rules is the process set under the Joint Ethical Convention between the IMA and Pharma Israel. As noted in our answer to question 1.6, this process may be relevant only to a limited aspect of pharmaceutical advertising (advertising by physicians or through promotional materials which are normally disseminated to physicians rather than to the general public). There is no statutory rule limiting the MOH discretion to investigate matters that may constitute a breach of both the law and the Convention and are already being assessed by an inquiring committee set under the Convention and there is no reported practice in this regard in Israel. There is also no reported practice on whether the MOH would take up matters based on an adverse finding of an inquiring committee set under the Convention.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

In the event that an advertisement is published in violation of the statutory pharmaceutical advertising rules or of other laws (for example, if such advertisement includes inaccurate information, it may violate the Consumer Protection Act, 1981 and/or the Commercial Wrongs Act, 1999), one of the legal doctrines and causes of action which, a competitor may possibly employ in direct legal action against the advertiser, under certain conditions, is an unfair competition claim, under which Israeli law is termed an unjust enrichment claim. The exact conditions under which an unfair competition claim may be so brought, if at all, or whether the publication of an advertisement may amount to unfair competition, even in the absence of a violation of any statutory rule, are complex questions which are yet to be fully decided by the Israeli Supreme Court. For example, in the recent case of CA 3322/16 IDI *Insurance Company Ltd. v. Israel Insurance Agents Association* (April 30, 2017) the Israeli Supreme Court left open the question of whether an advertisement which includes factually false information in violation of the Commercial Wrongs Act may also amount to unfair competition giving rise to an unjust enrichment claim. Under an unjust enrichment claim, if successful, a competitor might be entitled to disgorge profits made by the advertiser in consequence of the infringing advertisement, and it might also be entitled to an injunction stopping the further publication of the infringing advertisement.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Under section 28(a) of the Preparations Regulations, the advertising of a medicine must not contradict the registration of the product and must not attribute to it unapproved indications. As mentioned in answer to question 1.2, advertising is defined to include the provision of information in any form. In addition, section 28(a) does not include a distinction between advertising to the general public and advertising to healthcare professionals. Thus, literal interpretation of the Preparations Regulations may suggest that information about a medicine may not be made available at all either to the general public or to healthcare professionals before that product is registered in the Israel Drug Register or with regard to off-label information. However, such interpretation would not make much sense and is presumably not in line with Israeli practice. Among others, with respect to providing information prior to registration, the Joint Ethical Convention between the Israeli Medical Association (IMA) and Pharma Israel provides that pharmaceutical companies "may not carry any marketing activity with respect to a medicine that has not yet been registered in Israel. However, a pharmaceutical company would be entitled to provide scientific information, excluding aspects of sales promotion, while indicating the regulatory status of the product [and] subject to the updated regulation rules" (section 91 of the Convention). In addition, a physician lecturing at a scientific meeting (whether sponsored by the company responsible for the product or not) is presumably entitled under the Convention to relate to a medicine that has not yet been registered in Israel, provided that he clarifies the "relevant regulatory status" of the product (sections 13.d and 24). And, with regard to the provision of off-label information, MOH Procedure No. 137, while reiterating that "advertising of non-registered products or indications is prohibited", nevertheless provides that information directed to healthcare professionals (physician, pharmacist or nurse) may include, in addition to information in accordance with the registration conditions, "new information" from the medical or pharmaceutical professional and evidence-based literature, provided that "the purpose of providing the [new] information would not be to influence or encourage use not in accordance with the registration conditions in Israel" (section 3.1, 2.1). Moreover, with regard to information directed to healthcare professionals that are authorised to write prescriptions (via a password-protected website), the Procedure does not include the above proviso and simply provides that such information may include, in addition to information in accordance with the registration conditions, "additional information backed by professional literature at the discretion of the Registration Holder". Thus, the position under MOH Procedure No. 137 is that it is possible to make scientific off-label information available to healthcare professionals, or at least to healthcare professionals that are authorised to write prescriptions.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

As detailed in the answer to question 2.1, information on unauthorised medicines and/or off-label information may presumably be published if it constitutes scientific information, excluding aspects of sales promotion, and including an indication of the regulatory status of the product.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Under MOH Procedure No. 137, companies (and more accurately the Israeli Registration Holder of a medicine) are presumably permitted to provide information to a journalist about an unauthorised medicine if (a) the medicine is pending registration in the Israel Drug Register, and (b) the information is provided following an approach to the company by the journalist. Information so provided must presumably, among others, adhere to the information included in the registration application. Off-label information may not be provided to a journalist.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

As detailed in our answer to question 2.1, presumably, only scientific information, excluding aspects of sales promotion, may be sent to healthcare professionals by the company.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

In Israel, prices for non-registered medicinal products which are nevertheless approved by the MOH for import and marketing purposes (including, among others, for named-patient/compassionate use purposes) are regulated by the State, and the price lists of such medicines are publicly available (published on the MOH website).

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

In the absence of any specific provision in the Joint Ethical Convention between the IMA and Pharma Israel addressing this question, presumably only scientific information, excluding aspects of sales promotion, may be sent to institutions (see the answer to question 2.1).

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

There is no specific provision in the Joint Ethical Convention between the IMA and Pharma Israel addressing this question. However, under the Convention, physicians are permitted to serve as paid consultants to pharmaceutical companies "if the purpose of the consultation is to promote the medical knowledge, research and level of medicine in the country" (section 66) and presumably this might include involvement in market research exercises concerning possible launch materials for products or indications as yet unauthorised. The company may pay a physician consultant an "appropriate financial reward" in exchange for his consultation. The payment must be "appropriate to the professional status of the physician and extent of work performed by him" (section 68). No guideline has been issued to date in Israel on the market research of medicinal products.

Under MOH Guidelines (Circular No. 13/2018 (October, 2018)), any work by an employee of a public health institution for an external company requires specific approval in advance from the administration of the health institution, which will not be provided if there is risk of a conflict of interest.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Under the Preparations Regulations, advertisements in professional scientific journals must prominently include the approved indication for the product and refer to the information included in the patient leaflet and physician leaflet (if such leaflet was required for the product) and to its/their reference leaflet/s. Under MOH Procedure No. 137, information directed to healthcare professionals must be, among others, up-to-date.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

As detailed in the answer to question 2.1, under the Preparations Regulations, advertisements must not contradict the registration of the product and must not attribute to its unapproved indications. Under MOH Procedure No. 137, information directed at healthcare professionals may include scientific information which is new and is not mentioned in the product's patient or physician leaflet, as further detailed in the answer to question 2.1. Under the Joint Ethical Convention between the IMA and Pharma Israel, promotional material disseminated or published in any way by pharmaceutical companies must be "professionally edited" and adhere not only to the requirements under the Israeli legislation, but also to "globally accepted high ethical standards" (section 84). In addition, among others, any information included in promotional material must not be misleading "in the manner in which it is presented" (section 85).

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Under the Joint Ethical Convention between the IMA and Pharma Israel, a physician will not promote, market or advertise pharmaceutical products in any way whatsoever and will not "lend his name, academic title and professional position in favour of economic interests of any commercial body" (section 81). Normally, these restrictions would apply also with regard to a scientific union/society. However, in unusual circumstances detailed in the Convention, a scientific union/society (but not an individual physician) may advertise a commercial product (section 82).

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There is no specific requirement under Israeli legislation or ethical rules to support comparative claims with "head to head" clinical trials. However, under the GSL Regulations, comparative claims in advertisements (which can be made only between products with identical APIs) must be based on comparative legal studies published in peer reviewed scientific journals which establish the superiority of one of the compared products based on a uniform basis for comparison with regard to their efficiency. In addition, as previously mentioned, under the Joint Ethical Convention between the IMA and Pharma Israel, promotional material presented by pharmaceutical companies must adhere not only to the requirements under the Israeli legislation but also to "globally accepted high ethical standards".

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

See the answer to question 3.4. In addition, under MOH Procedure No. 24, a comparative advertisement of a non-prescription product must not create an artificial advantage or claim for general supremacy based on a limited comparison and an assertion that a product is the "most sold" or "one of its kind" must be factually supported. From the perspective of the Israeli Trademark laws, it is yet to be decided if using another company's brand name in a comparative advertisement may be excluded from trademark infringement. However, in CA 8483/02 *Alonial v. McDonald*, PD 58(4) 314, the Israeli Supreme Court favourably considered such an approach, provided that the comparison is based on accurate information and the advertisement does not unfairly discredit the competitor.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Under MOH Procedure No. 137, a link to or information from "the medical or pharmaceutical professional and evidence-based literature" may be made available to healthcare professionals (physician, pharmacist or nurse), provided that such information does not contradict the information in the product's patient and physician leaflets and as further detailed in our answer to question 2.1. In addition, with regard to healthcare professionals that are authorised to write prescriptions (via a password-protected website), any "information backed by professional literature" may be

made available, provided that it is delivered in addition to information in accordance with the registration conditions. In addition, under the Joint Ethical Convention between the IMA and Pharma Israel, companies that are disseminating promotional materials to physicians are actually required to provide them also with "scientific background material" relating to the promoted medicine (section 86).

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There is no reference in Israeli legislation or ethical rules to "teaser" advertisements and presumably such advertisements are permitted.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

In the absence of any reference in Israeli legislation or ethical rules to such scenarios, presumably where use of Product A in combination with Product B is part of the approved indication of Product A but not of Product B which is separately authorised to a different company, the holder of the MA for Product A is nevertheless permitted – and, moreover, obligated (see answers to questions 3.1 and 6.4) – to refer to the combination use in any permitted provision of information with respect to Product A. With respect to the holder of the MA for Product B in such circumstances, presumably he may refer to the combination use in communications directed to healthcare professionals, or at least to healthcare professionals that are authorised to write prescriptions, but not to the general public (see answer to question 2.1).

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Under MOH Guidelines (Circular No. 13/2018 (October, 2018)), which most of its provisions purport to apply to any and all public and private health institutions operating under a MOH permit and affiliated bodies, and for their employees, the default rule is against accepting samples of medicinal products. Accepting samples of medicinal products for demonstration purposes only is permitted subject to coordination in advance and in writing with the administration of the health institution. Accepting samples of medicinal products "in special cases in which a healthcare professional needs to have samples in his clinic… and the only option to accept them is directly from a representative of the commercial company", is permitted subject to approval in advance and on a case-by-case basis by the MOH Supreme Committee for Commercial Contacts with External Companies.

Under the Joint Ethical Convention between the IMA and Pharma Israel, it is permitted to provide physicians with samples of medicinal products in accordance with the following conditions: (a) the samples will be clearly marked as not-for-sale physician samples; (b) the physician will not be given any consideration by the company in exchange for receiving the samples; (c) the physician will not be given samples in commercial quantities; (d) the physician will not collect any payment from a patient in exchange for a sample provided to him; and (e) the activity is in line with the policy of the health institution in which the samples are intended to be distributed.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Under MOH Guidelines (Circular No. 13/2018), an employee governed by the Circular is not permitted to accept from a medical representative "any reward, incentive or personal benefit of any kind whatsoever, including funding of travel to conventions, stationary equipment and food/beverage items" (section 14.6).

Under the Public Service (Gifts) Law, 1979, a civil servant (including healthcare professionals employed by the State or the Sick Funds) is permitted to accept, while performing his duties, only "a low value and reasonable benefit that was given according to what is customary under the circumstances". In the event that a civil servant is offered a benefit that does not meet these requirements, he must either refuse to receive the benefit or immediately give notice of receiving the benefit. In the latter case, the benefit will generally become the property of the state. Failure to give notice is a criminal offence.

Under the Joint Ethical Convention between the IMA and Pharma Israel, a physician is permitted to be given only "gifts of nominal value which are meant to serve directly the physician's work, or symbolic gifts which are part of an acceptable social culture or etiquette" (section 50). Any personal benefit that does not meet these requirements must not be given or accepted. The Convention further stresses that it is prohibited to give any support to a physician (or a health institution) on the condition of advancement of an interest of the company or any other commercial body (section 53).

Under the Israeli Penal Code, gifts or donations of money given to a healthcare professional who is employed by a government hospital or a Sick Fund, if found to have been given in consideration for an action by him related to his duties, would constitute criminal bribery.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Under MOH Guidelines (Circular No. 13/2018), it appears that, in principle, a general-purpose donation of money or equipment by a commercial body to a health institution is permitted (section 15).

Under the Joint Ethical Convention between the IMA and Pharma Israel, a health institution, a clinic or a hospital department may be given "financial support or valuable contribution for the advancement of medical research, improvement of treatment, research and patients' treatment or for the betterment of medical equipment, as long as their acceptance would not impair the

professional independence of the physicians who will utilise the support and contribution, and as long as all the relevant rules guaranteeing full transparency and documentation are maintained" (section 51). As mentioned in our answer to question 4.2, the Convention further stresses that it is prohibited to give any support to a health institution (or to a physician) on the condition of advancement of an interest of the company or any other commercial body (section 53).

On the other hand, a commercial body may not fund in any way, directly or indirectly, approved positions or salaries to employees in a health institution which are not directly related to an approved research funded by it (section 13.5 of the Circular; an identical prohibition appears in section 62 of the Convention).

Under the Circular, a health institution or a recognised scientific union/society may accept funding from an external body to hold a scientific meeting/convention in Israel, provided, among others, that the healthcare organisation (and not the external body) initiates the scientific meeting/convention, that it does not include unrelated activities such as entertainment or trips, and that an effort is made to allocate the funding between at least three unrelated external bodies, as further detailed in the Circular (section 11).

Under the Convention, a scientific union/society or an employer may also be given a scholarship, including for a continuing education programme abroad, "for the advancement of the general knowledge of a physician or a number of physicians", provided that the physician/s who will utilise the scholarship is/are dually elected by the scientific union/society/employer and not by the company, and that the scholarship payment is made to the scientific union/society/employer and not directly to the elected physician/s (section 55). A scientific union/society or a physician may not be given any funding for any social activity of medical staff, including team-building activities (section 52), or any funding or other benefit in exchange for allowing visits by the company's medical representative (section 54).

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Israeli legislation and the Joint Ethical Convention between the IMA and Pharma Israel do not specifically address the provision of medical or educational goods and services to healthcare professionals. However, as mentioned in our answer to question 4.2, under the Convention, gifts "which are meant to serve directly the physician's work" must be "of nominal value" and the professional independence of the physician must be maintained. Presumably, as long as these conditions are adhered to, the provision of medical or educational goods and services to healthcare professionals would not be regarded as illegitimate merely because changes in prescribing patterns have occurred.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Israeli legislation and the Joint Ethical Convention between the IMA and Pharma Israel do not address the offering of a volume-related discount to institutions purchasing medicinal products. Such scheme is therefore permitted, subject to Israeli competition rules.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Under MOH Procedure No. 24, it is prohibited to advertise or promote the sale of medicines by offering to provide an additional product of any kind in exchange for their purchase. However, arguably, this prohibition only relates to end consumers and not to institutions. In any event, package deals are presumably permitted, subject to Israeli competition rules which may address tying arrangements depending on their anti-competitive effects.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

There is no reference in Israeli legislation or ethical rules to the offering of a refund scheme if the product does not work and presumably such a scheme is permitted.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

As noted in our answer to question 4.3, under the Joint Ethical Convention between the IMA and Pharma Israel, pharmaceutical companies may sponsor continuing medical education, including abroad, by providing a scientific union/society or an employer a scholarship, provided that the physicians who will utilise the scholarship are dually elected by the scientific union/society/employer and not by the company and that the scholarship payment is made to the scientific union/society/employer and not directly to the elected physicians.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

As mentioned in our answer to question 4.2, under the Israeli Penal Code, any benefit given to a healthcare professional who is employed by a government hospital or a Sick Fund, if found to have been given in consideration for an action by him related to his duties, would constitute criminal bribery. In addition, under the Public Service (Gifts) Law, 1979, a civil servant (including healthcare professionals employed by the State or the Sick Funds) who is offered, while performing his duties, a benefit that exceeds "a low value and reasonable benefit… according to what is customary

under the circumstances", must either refuse to receive the benefit or immediately give notice of receiving the benefit, and in the latter case the benefit will generally become the property of the state. Failure to give notice is a criminal offence. Under the Joint Ethical Convention between the IMA and Pharma Israel, a physician must not be given any personal benefit that exceeds "gifts of nominal value which are meant to serve directly the physician's work, or symbolic gifts which are part of an acceptable social culture or etiquette". In addition, a physician or a health institution may not be given any support on the condition of advancement of an interest of a company or any other commercial body. In accordance with MOH Guidelines (Circular No. 13/2018), an employee governed by the Circular is not permitted to accept from a medical representative "any reward, incentive or personal benefit of any kind whatsoever, including funding of travel to conventions, stationary equipment and food/beverage items" (section 14.6).

As elaborated in the answers above, the MOH is the main competent authority for pharmaceutical advertising. The Joint Ethical Convention between the IMA and Pharma Israel provides guidance with regard to aspects that concern both pharmaceutical advertising and practices that are prone to bribery/corruption concerns. An inquiring committee set under the Convention may address violations that relate to both these aspects. There is no statutory rule limiting the anti-bribery enforcement authorities (i.e., the police and State prosecution) discretion to investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation and are already being assessed by an inquiring committee set under the Convention and there is no reported practice in this regard in Israel.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The Joint Ethical Convention between the IMA and Pharma Israel distinguishes three categories of scientific meetings: (a) a scientific meeting held in Israel and initiated by a scientific union/society; (b) a scientific meeting (to which at least 30 physicians have been invited or is held outside the premises of a health institution) in Israel and initiated and financed by a pharmaceutical company; and (c) a scientific meeting (or a continuing education programme) abroad financed by a pharmaceutical company.

Under category (a), the physician attending the meeting, or his employer, must pay the registration fee and the pharmaceutical company cannot be involved. If the meeting includes lodging and/or social activity, the delegates themselves must pay a portion of the hospitality (including lodging and meals) fees, as determined by the scientific union/society. The scientific union/society may also exempt "certain groups" of delegates from paying delegation fees "for special reasons to be noted". A person accompanying a delegate physician and who is also attending the meeting must make full payment to cover his participation. A pharmaceutical company may sponsor or co-sponsor the meeting, under the conditions detailed in the Convention.

Under category (b), the meeting may not include lodging. Under category (c), the company, through the scientific union/society or employer that elected the delegate physician, may reimburse part or all of the physician's "actual expenses with regard to his travel and participation in the meeting or continuing education program" (section 29 of the Convention). A company may not fund (in money or money's-worth) any activity by a physician that is not directly related to the meeting.

Under both categories (b) and (c), the company may not invite accompanying persons to a meeting. The Convention further stresses that a pharmaceutical company may not finance any expenditure related to the participation of an accompanying person in professional events organised of its own initiative.

Under all categories, the company may pay a reasonable fee to a lecturer in a meeting (which under category (a) must be elected by the scientific union/society). The company may also reimburse the lecturer for his actual expenditures related to the preparation of his lecture.

Under MOH Guidelines, employee enrolment in a meeting/convention funded or organised by a commercial body may be approved only if the meeting/convention is not intended for marketing/sales promotion (if the meeting/convention is held abroad and organised by a single commercial body in an area in which additional external bodies operate, it will be considered as intended for marketing). In addition, if the meeting/convention is held in Israel, employee enrolment may be approved provided that (a) at least 75% of its activity would be dedicated to professional topics, (b) meeting/convention days without scientific/professional activity would be funded by the delegate employee, and (c) the meeting/convention will not include "entertainment activity" (section 11.2). If the meeting/convention is held abroad, employee enrolment may be approved if, among others, the employee is not employed by the external body, does not provide it consultation and has no interest in it, and has no impact on the purchasing decisions of the health institution.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

See the answer to question 5.1. In addition, it has been clarified that paying a healthcare professional for his time is presumably not permitted.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

In the event that a complaint is filed under the Joint Ethical Convention between the IMA and Pharma Israel, a company may be held responsible for any violation of the Convention in a meeting directly organised by it. However, the extent of "direct organisation" will need to be analysed and the scope of the liability will be dependent on whether the company knew or should have known of the violation. Extending liability for a company which sponsors a meeting, as opposed to a meeting which is organised by the company, seems far-fetched absent proof that the company was somehow involved in introducing the contents which violates ethical obligations.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Under the Joint Ethical Convention between the IMA and Pharma Israel, payments to physicians for providing expert services are permitted subject to maintaining the physician's professional independence and further conditions stipulated in the Convention. The purpose of paid consultation by a physician to a pharmaceutical company must be to "advance the medical knowledge, research and level of medicine in the country" (section 66). A physician may serve as a sole consultant to the company or as a member of an advisory board which may include up to 15 physicians among additional experts. As previously mentioned, the company may pay a physician consultant an "appropriate financial reward" in exchange for his consultation. The payment must be "appropriate to the professional status of the physician and extent of work performed by him".

As previously mentioned, under MOH Guidelines (Circular No. 13/2018), any work by an employee of a public health institution for an external company requires specific approval in advance from the administration of the health institution, which will not be provided if there is risk of a conflict of interest.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

MOH Procedure No. 14 which regulates clinical trials in humans, including phase IV trials (which include post-marketing surveillance studies), does not include a prohibition on payments to researchers, provided, among others, that with regard to any trial taking place in a health institution, any reward to a researcher "directly or indirectly related to the trial" is approved in advance by the director of the health institution (section 7.1). The general rules that govern clinical trials also govern phase IV trials. Among others, in order to be approved, the current medical and scientific data must justify the performance of the trial. In addition, there must not be any conflict of interest between the performance of the trial at a health institution by a commercial body and a researcher employed by the institution.

Notwithstanding the above, under the Joint Ethical Convention between the IMA and Pharma Israel, payments (including money's-worth or research grants) may not be made directly to a physician-researcher but only via the physician's scientific union/society/employer. Any payment must not be dependent on the results of a clinical research. No payment may be made to a physician which is not involved in the research, for merely referring patients to the research. All payments must be detailed in writing. In addition, the Convention stresses, among others, that post-marketing surveillance studies must not be performed "when the scientific or professional background is deficient or absent, and the research is intended only as a means to promote the sale of the medicine and to influence physicians (section 40)".

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

There is no specific reference to this issue in the Joint Ethical Convention between the IMA and Pharma Israel. Presumably, at least until if and when this issue is specifically addressed in Israel, responding to market research questionnaires may be regarded as consultation work and, as elaborated in the answers above, paid consultation by physicians is permitted under the Convention subject to restrictions on the level of payment and the purpose of the consultation (and, with respect to employees of public health institutions, the work will require specific approval in advance from the administration of the health institution, which will not be provided if there is risk of a conflict of interest). In addition, presumably the promotional materials involved would need to adhere to the conditions detailed in the answers to questions 3.1 and 3.2.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Advertising of non-prescription medicines to the general public is permitted subject to approval in advance by the MOH and in accordance with MOH Procedures. Among others, under MOH Procedure No. 24, the information appearing in the advertisement must be correct, accurate, clear and in accordance with the indication that was approved for the product. An advertisement must not be misleading, intimidating, create tensions, and insinuate that the medicine would provide qualities or advantages not in accordance with the approved indication or encourage uneducated use. Generally, advertising to minors is prohibited. Comparative advertisements may be approved under the restriction detailed in answers to questions 3.4 and 3.5.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Generally, advertising of prescription-only medicinal products to the general public will not be approved by the MOH. In extraordinary cases in which it is extremely important to disseminate explanatory materials that have an added value over the patient leaflet, the MOH may approve their publication, provided that they are delivered to the patient by the treating physician in person and together with the prescription to the medicine.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are permitted in accordance with MOH Procedure No. 134, as updated in March 2019. Among others, such campaigns are permitted only with regard to medical conditions that have an approved medicinal treatment in Israel. They must not mention trade names or generic names of prescription-only medicines, encourage or recommend the purchase or use of any medicine, persuade by intimidation or be directed to minors or helpless people. Disease awareness and prevention campaigns for AIDS must be coordinated with the MOH. Companies may perform awareness campaigns themselves or finance awareness campaigns performed by third parties, provided, among others, that they do not influence the contents thereof and that no specific medicine is mentioned (however, the logo of the Registration Holder may be displayed in campaign events, together with a statement to the effect that the event is funded by the company).

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Under MOH Procedure No. 137, as updated in August 2016, it is permitted to hold a launch event open to the media (but not to the general public) during the period after the registration of the medicine in the Israel Drug Register and until the approval of the first batch of the medicine for marketing. Information delivered by the Registration Holder during the event must not be intended or used to encourage prescribing of prescription medicines and it must be factual, balanced, supported and strictly in accordance with the registration conditions. In addition, among others, such information must refer to the medicine's side effects as listed in the patient leaflet, be non-commercial and not slander competitors and, in the event that there are additional therapies/medicines, these should also be mentioned. The event must be reported in advance to the MOH and the media must be briefed on the requirements of the Procedure. It is prohibited to refer to developments in relation to as yet unauthorised medicines or unauthorised indications.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Under MOH Procedure No. 137, business-economic information to the shareholders of the mother company or a Registration Holder, delivered to business/economic media read by the general public, must be "in a business context" and "in accordance with any law".

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

It is permitted for companies to fund patient organisations, provided, among others, that they preserve their independence, do not advertise prescription-only medicines and do not encourage patients to seek a particular treatment from the treating physician, and otherwise abide by MOH procedures, as further detailed in MOH Procedure No. 137.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Under MOH Procedure No. 137, with respect to patients that have been prescribed a prescription-only medicine, companies may provide certain items intended to enhance accessibility to permitted information with regard to the medicine, in order to improve educated use and compliance, such as: leaflets; self-monitoring diaries; instruction manuals; magnets with administration instructions; and guidance short films and so on.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Under MOH Procedure No. 14, as amended in May 2017, controlled and prospective medical trials, which involve one or more medical interventions and an examination of the impact on health, must generally register with the MOH website: https://my.health.gov.il/CliniTrials/Pages/Home.aspx. Registration must be made after approval of the trial by the Helsinki Committee and before the relevant health institution can approve the start of the trial. The information on trials displayed on the MOH website includes information with regard to the illness/medical condition, the evaluated intervention, the manner in which the trial is conducted, criteria for inclusion/non-inclusion in the trial, a list of the health institutions where the trial is performed and contact details via which patients can inquire if they may be eligible to take part in the trial and receive additional details. Results of clinical trials are not published on the MOH website. In exceptional cases, feasibility trials may be exempted from registration on the MOH website, due to intellectual property concerns, provided that the trial has also not been registered on the US NIH website.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Under section 40A(a) of the National Insurance Law, 1994, an Israeli entity (that is, an Israeli resident or a corporation that is registered in Israel and is a Registration Holder, a manufacturer, importer or marketer of a medicinal product, or a corporation which controls or is controlled by any of them), that donates (money or money's-worth) any sum to a health establishment, or donates to a healthcare professional a yearly sum exceeding approximately NIS 2,500 (approximately USD 700; the exact sum is updated yearly based on the increase in the consumer price index), must provide a yearly report to the Minister of Health, detailing each donation, the identity of its recipient, the sum or value of the donation and its purpose (with regard to a money donation) or its description (with regard to a money's-worth donation). The Ministry of Health publishes on its website a yearly list of all reported donations.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The Joint Ethical Convention between the IMA and Pharma Israel only includes a general provision which, as previously mentioned,

conditions permitted financial support by companies on maintaining "the relevant rules guaranteeing full transparency and documentation".

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

The statutory reporting obligations that apply to an Israeli entity are not conditioned in any way. Moreover, corresponding reporting obligations apply directly to the health establishment or healthcare professional that received a donation (in fact, their reporting obligations extend also to donations received from a foreign resident or corporation).

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

In principle, internet advertising is regulated similarly to advertising in any other medium.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Under MOH Procedure No. 137, sections/pages on an online medium that are intended only for healthcare professionals that are authorised to write prescriptions must be password-protected, as further detailed in the Procedure.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

A company may be held accountable for a violation of the advertising rules by the content of independent websites that may be accessed by a link from a company-sponsored site. With regard to the scenario of reverse linking of independent websites to a company's website, presumably the obligation to password-protect content intended for healthcare professionals on the company's website would prevent a violation of the advertising rules.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Under MOH Procedure No. 137, a Registration Holder may place on its website, for general access, a list of the pharmaceutical products registered under its name (commercial name and API), and permitted disease awareness information, as further detailed in the Procedure. In addition, the Registration Holder may place on its website, for access by patients which were prescribed a prescription-only medicine (on a password-protected section), information intended to improve educated use and patient compliance, as further detailed in the Procedure.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

Under MOH Procedure No. 137, the Registration Holder is permitted to place permitted information in accordance with the Procedure on "internet sites and social media belonging to the Registration Holder or funded by it in Israel".

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

MOH Circular No. 13/2018 (Rules for commercial engagements by the health institutions) was published in October 2018 and entered into force on November 1, 2018. Unlike its 2010 predecessor, which regulated commercial engagements applied only to units and health institutions of the MOH and the Clalit Sick Fund (which consented to be governed by it), most of the provisions of the new Circular purport to apply to any and all public and private health institutions "operating under a MOH permit" and affiliated bodies. Among others, with respect to activities by medical representatives, the new Circular contains draconian provisions which far exceed the ethical rules set in the Ethical Convention between the IMA and Pharma Israel. Among others, section 14.5.2 forbids one-on-one meetings between medical representatives and physicians (until November 1, 2019 (at least), one-on-one meetings are allegedly permitted if "there is a reason for which this section cannot be abided and subject to approval in advance by the Director of the health institution (section 17). However, it is doubtful whether such approval may be obtained in practice). Following a petition to the Supreme Court filed by Pharma Israel, the MOH consented to disregard and amend another provision in the Circular which would have required medical representatives, among others, to undergo a course on ethics. On January 27, 2019, the MOH issued a letter to the directors of the health institutions, stating that an amended Circular is to be published, in which the requirement with respect to training of medical representatives (which is not upheld) will be replaced with a "recommendation with regard to the extent and contents of the training [required] with regard to the ethical rules".

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

Apart from the upcoming amendment of MOH Circular No. 13/2018 discussed above and possibly a further evaluation by the MOH of the limitations imposed on the work of medical representatives, there are no significant developments in the field of pharmaceutical advertising expected in the next year.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

Apart from MOH Circular No. 13/2018 discussed above, there are no general practice or enforcement trends that have become apparent in Israel over the last year or so.

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**Liad Whatstein, Founding Partner**.

Liad is one of Israel's best-known and most respected IP lawyers and has been involved in some of Israel's most complex and widely publicised patent, trademark and copyright disputes. Liad is broadly recognised by clients, peers and international directories as one of Israel's most successful litigators. He has litigated cases for the most innovative pharmaceutical companies in connection with many blockbuster drugs, supervised complex experiments and has worked extensively with some of the world's leading experts. In addition, Liad is extensively involved in patent prosecution work and leverages his unrivalled litigation experience to obtain enforceable patents and develop creative prosecution strategies. Liad also represents many of the world's leading brand owners in enforcing their trademarks and litigated some of Israel's landmark copyright cases.

Liad has been consistently described by *Chambers*, *The Legal 500*, *IAM*, *Who's Who Legal*, *WTR* and other leading directories as a "truly great litigator" and a "celebrated name" who knows how to deliver results to clients. Liad is also a prolific writer and was the Chairman of the IP Chapter of the Israel Bar Association.

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Uri has been practising IP law for over a decade and specialises, in particular, in regulatory and non-contentious work in the Life Science field. Uri also has a very strong theoretical knowledge of patent laws with a unique expertise in matters relating to Patent Term Extensions (PTE) and Data Exclusivity. He successfully briefed and argued cases at the Patent Office, District Courts and the Supreme Court on these matters. He was also extensively involved in advocating legislative changes in patent legislation before the Knesset Law Committee. In addition to his patent and regulatory practice, Uri is also involved in numerous trademark cases involving look-alikes and protection for non-traditional trademarks. Uri published several chapters and articles on IP law and most recently the Israeli chapter of Patent Transactions in the Life Sciences (Globe Law and Business, October 2014).

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Liad Whatstein & Co. is internationally recognised as Israel's foremost IP and life science firm. The firm is recognised as the first choice for complex life science litigation and PTO opposition proceedings and regulatory issues representing many of the global international pharmaceutical companies. In addition, the firm also manages large patent and trademark portfolios of major international clients and represents Fortune 500 clients in a broad range of additional industries and technologies including agrochemical and chemistry, medical devices, computer hardware and software, electronics, defence technologies, and others. The State of Israel also entrusted the firm with its high-profile patent cases attesting to the firm's prominent position and recognition by peers. The firm also handles one of the largest anti-counterfeiting practices in Israel and represents, among others, pharmaceutical companies in legal and administrative proceedings against the sale of fake drugs. The firm has an excellent working relationship with the enforcement agencies and also assisted in developing their working guidelines and procedures.

# Italy

Sonia Selletti

Astolfi e Associati Studio Legale

Annalisa Scalia

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products is governed by art. 113 *et seq*. of legislative decree no. 219, 24 April 2006 ("Code on Medicines", which implements directive 2001/83/EC and subsequent amendments) and by a series of secondary regulatory sources including Guidelines issued by the Ministry of Health (MOH) on the use of new means of communication such as digital and social tools in advertising over-the-counter medicinal products (OTC), Guidelines issued by the Italian Medicine Agency (AIFA) on conferences, congresses, and filing of advertising material. Specific AIFA Guidelines on the advertising of medicinal products to healthcare professionals (HCPs) are currently being approved.

Advertising of medicinal products is also subject to the general provisions on advertising set out in Legislative Decree 206/2005 ("Consumer Code") and Legislative Decree 145/2005 on misleading and comparative advertising (implementing directive 2005/29 which amended directive 84/450).

Italy also has self-regulatory codes such as the Farmindustria Code and the Code of the self-regulatory advertising institute (IAP Code), which set out specific regulations on the public advertising of medicinal products (art. 25).

### 1.2 How is "advertising" defined?

Art. 113 of the Code on Medicines defines the "advertising of medicinal products" as "any informative, customer acquisition or persuasive action whose purpose is to promote the prescription, supply, sale or consumption of medicinal products". This is a broad definition, which covers advertising to the public (allowed for OTC and SOP non-prescription products, prohibited for prescription products) and advertising to HCPs authorised to prescribe medicinal products (physicians) or to dispense them (pharmacists), which also includes visits by medical sales representatives, delivery of samples, sponsorship of scientific meetings and congresses organised for HCPs. The laws apply to any party that performs the activity defined as "advertising of medicinal products" and not only to the holder of the Marketing Approval (MA), since their purpose is to safeguard public health. The Court of Cassation recently issued ruling no. 10892 of 7 May 2018 with reference to an unauthorised public advertisement, with which it stated that the sanction should not only be imposed on the producer, but also on those who spread the advertisement.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

According to art. 126 of the Code on Medicines, every MA Holder (MAH) must have a scientific office that oversees the information released to the market on its medicinal products, headed by a person who meets the legal requirements, which must ensure that the company's advertising is legally compliant. This scientific office must operate independently of the marketing division. There is no sign-off requirement on promotional copy, but procedures providing documented evidence that the scientific service has verified the copy and activities are advisable, because breach of the verification obligation is subject to administrative penalties. The Farmindustria Code envisages a system for annual certification of the correctness of scientific information activities.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no legal requirements for companies to have SOPs. It is advisable for companies to have SOPs governing the roles, duties and processes for assessing and approving the advertising of medicinal products, especially to HCPs, intended to (legitimately) promote the prescription of their products. Relations with HCPs, and with the public bodies in which they work, constitute a delicate question as regards the prevention of certain offences (e.g., corruption, bribery), in view of companies' administrative and also criminal liability under legislative decree 231/2001 (governing the responsibility of entities and companies) and the very heavy sanctions that may be imposed. Procedures are also important for the certification envisaged by the Farmindustria Code. Procedures should adopt the principle of separation of roles and powers so that each process provides for multiple parties to be involved in the various roles, thus facilitating control. The Code on Medicines sets out subjective requirements (e.g., degrees in medicine, chemistry, pharmacy, etc.) for the crucial functions involved in advertising to HCPs (e.g., sales representatives and the head of the scientific office).

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

Public advertising is allowed for OTCs and SOPs, subject to prior approval by the MOH, after consultation with the relevant Commission of Experts. The opinion of the Commission is not mandatory if the advertisement cannot be approved due to: a manifest breach of the Code on Medicines; an intended use for diffusion through the daily or periodical press, or through the radio, and has been approved by a recognised self-regulatory body; and being part of another advertisement that already has approval based on the opinion of the Commission. Approval is requested through an application to the MOH and is deemed approved (by tacit consent) after 45 days from the date of presentation of the application. Express approval may be given. The advertisement must bear the approval date (in the case of express approval) or the date of the application (in the case of tacit consent). If during the 45 days the MOH rejects the application or approves it in part, the applicant has 10 days to present a rebuttal. If the advertisement has been definitively rejected (in whole or in part), the only possibility is to apply to the courts (administrative court). If the advertisement has been approved in part, only the part that has been approved may be used.

For advertising to HCPs, all advertising targeting HCPs (with the exception of the reproduction of the Summary of Product Characteristics – SmPC) may be used 10 days after filing with the AIFA (filing shall take place exclusively online from 1 June 2018) in the absence of objections. Gadgets must also be filed (e.g., pens, stickers, USB pen drives).

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The authorities have supervisory powers enabling them to intervene even after the approval of advertising (to the public and to HCPs). In this case, they must provide adequate grounds for their intervention. Review/withdrawal orders may also be issued by other advertising authorities (Italian Competition Authority) or by the courts in the event of disputes among companies. The intervening authority may order the company to change the advertisement and/or to cease publication, and to also issue a corrective statement (in daily newspapers, on the company website, etc.). Appeals against the orders of the healthcare authorities and the Competition Authority may be made to the administrative tribunal, while appeals against court rulings may be made to a higher court (e.g., court of appeal).

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Failure to comply with the rules governing advertising to the public is liable to fines ranging from €2,600–€15,600 (art. 148.5 Code on Medicines) and from €10,000–€60,000 when in the press or in radio-television programmes, which do not have advertising aim, images of a medicinal product are shown or the product is named in a context that could promote its consumption (i.e., product-placement).

Failure to comply with the rules governing advertising to HCPs is liable to fines ranging from €2,600–€15,600. For medicinal products that are reimbursed by the National Health System (NHS), reimbursement may be suspended for a period ranging from 10 days to two years, depending on the gravity of the breach. The suspension order is implemented after a complaint has been made to the MAH, who have 15 days to present a rebuttal to the AIFA (art. 148.18 and 19 Code on Medicines).

The healthcare authorities are: the AIFA for advertising to HCPs; the MOH for advertising to the public; and the Farmindustria Control Committee/Jury for self-regulation. Furthermore, consumer associations may apply to the Competition Authority to intervene with regard to public advertising of medicinal products. On 19 January 2017, the AIFA and the Competition Authority signed a memorandum of understanding to strengthen surveillance in the pharmaceuticals sector through mutual cooperation and coordination of their areas of intervention.

Anyone may report advertising deemed incompatible to the authorities. Competitors may also sue for unfair competition. The Court of Milan recently issued a ruling on the case of a generic drug manufacturer, which published a table listing its products (showing active ingredients, reimbursement class, name of the original product, price); the court considered that the publication of the table was a breach of advertising laws and an act of unfair competition due to the manner in which it was published, and because it referred to prescription drugs.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The authorities' approval and supervisory activities cannot be replaced by self-regulatory bodies.

Any decisions on advertisements or promotional activities (in favour of or against) already taken by a self-regulatory body (for example, by Farmindustria) are not binding on the authorities or courts; but they constitute elements to be considered when assessing the correctness of the advertisement and the company's conduct.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Advertising of medicinal products that is in breach of the Code on Medicines may constitute unfair competition from a variety of viewpoints: absence of approval; advertising that creates confusion; discredits or denigrates competitor products; advertising that takes undue advantage of the competitor's brand reputation; trade name; or other distinguishing element. The competitor may pursue a civil lawsuit to stop the use of the unfair advertising and obtain compensation for damages.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

The Code on Medicines (art. 114.1) prohibits "any advertising" of medicinal products in the absence of a MA issued in accordance with national or EU procedures (the principle also applies to indications extensions). Advertising to HCPs must always specify the classification for the purposes of supply, the price and the conditions for reimbursement by the NHS (art. 119.3). Filing of promotional materials without such information is not accepted, with the exception of advertising limited to the name of the medicine. For class C/nn medicines (for which NHS reimbursement conditions are yet to be negotiated) the SPC may be divulged to HCPs, because it has been approved and consequently is not subject to additional filing. The AIFA Guidelines of 11 February 2010 allow companies sponsoring congresses about their medicines to provide information on molecules still undergoing testing limited to the action mechanism, with no mention of the therapeutic indications as yet unauthorised, and, for international congresses, to divulge information compliant with the MA of other countries, pointing out that the medicine (or the new indication) has not yet been approved in Italy.

At conferences not sponsored by the company, the independent scientific community may discuss molecules of unlicensed medicines by virtue of the constitutional principles safeguarding scientific research and the freedom of expression of thought.

The off-label use of medicines may not be promoted. The company may only respond reactively to unsolicited requests and eventually send related documentation (not of a promotional nature, *cf.* question 2.4).

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

There is no prohibition on the publication in scientific journals of information on unauthorised medicines and/or for off-label use, on the condition that there is no promotional content/intention. Divulgation to the public of information on medicines indicating the commercial name or active ingredient is not allowed if the information comes, directly or indirectly, from the MAH; if it comes from a "lay" author it is assessed on a case-by-case basis to identify clearly the purpose and context. It is advisable to avoid divulgation to the public of information on the off-label use of medicines.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

The laws governing pharmaceuticals do not regulate press releases. The pharmaceutical company may not issue information to the public through press release on unauthorised medicines or on off-label use, with the exception of limited cases of information on research and development plans and financial data. The commercial name and active ingredient must not be named and each situation should be assessed on a case-by-case basis with regard to context, recipients and the possibility that the information might acquire a promotional profile.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Information on unauthorised medicines may not be sent to HCPs, since the law requires that information complies with the authorised SPC (art. 114.2 Code on Medicines). The company may send HCPs answers to specific and unsolicited requests for information about a particular medicine, which art. 113.2 of the Code on Medicines considers extraneous to advertising. It is essential that the company role be reactive and not proactive.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to Pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The above ECJ judgment has not had consequences in Italian law and practice, where access to unauthorised medicines is allowed in the cases envisaged by law, including importing from abroad, which is governed by MOH Decree 11 February 1997, under which a prescription is required for use by individual patients, subject to informed consent, but without the involvement of the pharmacy. The recent MOH Decree 7 September 2017 regulates the use of medicines that have not yet been authorised (subject to testing) or that already have a MA but are not available to patients (including for exceptional and unforeseen reasons, for a transitional period) if the company is willing to supply them free of charge. These hypotheses relate to compassionate use purposes.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

There are no regulations on this point. In our opinion, the company may not provide such information proactively and in promotional contexts, but only reactively in response to unsolicited requests from hospitals or healthcare bodies, doing no more than answering the request using documented and verifiable data.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

There are no guidelines on this topic. HCPs may be involved as expert consultants, both individually or as members of Advisory Boards, to give the company scientific support in preparing the

market launch of medicines. Their involvement may not be for the purpose of promotion or inducement to prescribe, and checks should be carried out to ensure there are no incompatibilities and/or conflicts of interests and to ascertain whether the prior authorisation of the entity should be sought if the professional is employed by a public entity (Legislative Decree 165/2001 and Law 240/2010). The Farmindustria Code (art. 4.1) allows the engagement of physicians as company consultants, as conference speakers and moderators and in conducting observational studies in educational activities (the list is not exhaustive), and on the condition that: there is a written contract; the nature of the service provided is specified; the remuneration is in line with fair market value; any travel and/or hospitality complies with the limits envisaged for conferences and congresses; the consultant discloses the relationship with the company on all occasions in which he/she writes or speaks in public about the topic to which the agreement refers; transparency obligations regarding Transfer Of Values (TOVs) are met; and documentation about the service provided is conserved for at least three years. It is advisable for the company to implement specific SOPs to govern these types of relationship with HCPs, in particular market research, where the boundary between scientific and promotional value may be extremely blurred.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

Under the Code on Medicines (art. 119.3), advertising of a medicinal product to HCPs must always include the authorised SmPC when the advertising is released, specify the classification of the medicine for the purposes of supply, the sale price and the conditions for reimbursement by the NHS. The AIFA deems that the practice of delivering the SmPC to the physician through the sale representatives does not replace the obligation for the SmPC to be included in every promotional instrument. As an exception to this rule, advertising to HCPs may be limited to the name of the medicine, with the specification of the common name of its active ingredient/s. The name of the MAH may be added to these indications, possibly followed by the name of the party who actually markets the product (e.g., the distributor).

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Advertising of medicines must be consistent with the information in the SmPC and with the documentation presented in the application for the MA or with its updates (arts 114.2 and 120.3 Code on Medicines). The information must be exact, complete, up to date and verifiable (therefore referred to published data). Exaggerated declarations, universal and hyperbolic assertions (such as "perfectly tolerated", "fully safe", "preferred medicine") are not allowed (art. 2.2 Farmindustria Code). Promotional mention of off-label data is not allowed. The AIFA guidelines of 2010 allow for information on molecules being studied to be presented on company stands at congresses and many companies present material on clinical development plans and study drawings.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The physician's Code of Conduct (art. 57) does not allow product endorsements, especially in promotional materials. Scientific papers published by physicians containing references to molecules or medicines may be reproduced in promotional materials only in the full-text version and with precise indication of the source (art. 120.4 Code on Medicines).

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There are no specific guidelines on this point. The law and self-regulation require that all information content in promotional materials for HCPs be demonstrable and based on objective elements. Among the conditions set out for comparisons to be legitimate, the law on comparative advertising (Legislative Decree 145/2007, art. 4 provides, *inter alia*: that comparisons must be between products that satisfy the same needs; based on elements that are objective; complete; verifiable; non-misleading; and do not discredit other companies' products.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Comparative advertising is governed by the above-mentioned Legislative Decree 145/2007. Conditions for licit comparative advertising are contained in art. 4 (see also question 3.4). Use of another company's brand name in comparisons is not prohibited *a priori*, but it should be assessed on a case-by-case basis. Reference to the other company's active ingredient is preferable.

AIFA practice allows in principle for a comparison of medicines in advertising to HCPs with no misleading elements, which compares medicines with: indications that are exactly the same; properties extracted faithfully from the SmPCs without partial references or distortions; and those containing the classification for the purposes of supply, the sale price and the conditions for reimbursement by the NHS. In our opinion, references to unauthorised indications in promotional contexts are not possible.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The distribution to HCPs of scientific papers and/or proceedings of congresses on medicines manufactured or marketed by the company is possible only after filing with the AIFA 10 days before use. Journals referred to in Medline, books and monographs referred to in OPAC SBN or in MAI, the official proceedings only of national or international congresses may be used as sources of scientific information, provided that they have been published and may therefore be verified by the HCPs.

Abstracts, posters, and work that has not been published and lacks a Digital Object Identifier (e.g. "in press"), as well as case reports and expert opinions may not be used, either as sources or, even less, as promotional material. In AIFA practice, issues of independent journals referred to in Medline that are published and distributed on a regular basis are considered to be advertising only when they contain a direct or indirect reference to a medicine or to its active ingredient and are distributed, in full or as reprints of individual articles, by the MAH. Divulgation of works with final approval from the Editorial Board published on the web in a definitive version and identified by DOIs, is allowed.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

The law does not provide indications regarding teaser advertisements. The content of the teaser would have to be assessed on a case-by-case basis, also with regard to the condition that all advertising must be transparent.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

This is a special case which must be evaluated on a case-by-case basis and in consideration of the entire context. In general terms, it can be seen that the holder of the MA for Product A (which is authorised for a particular indication to be used in combination with the Product B, and whose SmPC expressly refers to use with Product B) can promote the combination use; on the contrary, the holder of the MA for Product B (which is not authorised for a particular indication to be used in combination with the Product A, and whose SmPC does not expressly refer to use with Product A) cannot promote the combination use.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Samples of medicinal products – except those containing psychotropic or narcotic substances – may be provided only to physicians (including those working in hospitals) authorised to prescribe, and upon their prior request in writing (dated and signed). Samples are delivered only by sales representatives, with these limits:

- eight samples per year (two per visit) in the first 18 months after the launch of the medicine; and
- 10 samples per year (four per visit) after the first 18 months following the launch.

The Regions may also introduce limits on the number of samples, so the allowed quantities need to be checked at local level. Samples of medicinal products subject to reimbursement by the NHS must be indelibly marked "free sample – not to be sold" or a similar expression. Specific requirements apply for the box and label of the samples.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

The Code on Medicines prohibits the giving, offering or promising of pecuniary or in-kind rewards and benefits to physicians and pharmacists, unless these are of "negligible value" and related in some way to their work. The same principle applies in self-regulation, which quantifies the "negligible value" as €25 (per year per physician), while the regional guidelines set the limit at €20. The Farmindustria Code (art. 2.13) also prohibits the offer of economic incentives to HCPs to compensate for time taken away from their normal professional activities to attend congresses. Gifts with the name of the medicine or the company must be filed with the AIFA 10 days before distribution.

Within the above limits, the MOH Decree issued on 14 April 2008 allows the offer of high-quality scientific books, CD-DVDs or passwords for access to medical-scientific websites, subscriptions to indexed scientific journals of established publishers, registration to online medical-scientific newsletters. The Farmindustria Code is more restrictive: it states that if the value of the item is more than €25, the item may be given for free only to healthcare organisations (HCOs) (not to individual physicians) and must be purchased from the company at central level.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

This is a donation of money to HCOs. The donation is normally made for scientific purposes without any consideration or compensation for the company. It is essential to follow the compliance procedures of the public entity and to verify whether a notarial deed is required which depends on the amount of the donation (a notarial deed is not required for donations of a modest amount and the limit is assessed in relation to the capacity of the donor). The question of donations is a delicate one, since the donation must not represent, even indirectly, an incentive to prescribe or to encourage use of the company's medicines. It is advisable that the company implement SOPs to make the donation process transparent and secure, and to establish limits, for example, in cases where a tender for a medicine contract, an assessment of a medicinal product for inclusion in the hospital's list of products, or a clinical trial is underway. Gifts are not possible. The law does not prohibit donations in kind, but the principles referred to above with regard to the absence of compensation apply. Additionally, the Farmindustria Code (art. 2.15) allows the donation of instruments strictly related to the medical profession to universities, hospitals and clinics, and compatibly with the administrative procedures of the entity, with the exclusion of donations or bailments of interchangeable instruments – used in a different or alternative fashion with respect to diagnostic or therapeutic purposes – such as smartphones, tablets or similar, intended for personal use by physicians outside the HCO, or to be given to patients.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The allowed medical or educational materials are described in MOH Decree 14 April 2008 (*cf.* question 4.2). If the material satisfies the requirements of the decree, it could hypothetically also contain elements (documentable and verifiable) that lead HCPs autonomously to make changes in their prescribing patterns. It is always advisable to assess the material on a case-by-case basis to ensure that it is not of a promotional nature. Services may not be provided in favour of HCPs, as this would be in breach of art. 123 of the Code on Medicines, and might also constitute an unlawful act of bribery (art. 170 Royal Decree 27 July 1934, no. 1265).

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

In connection with advertising, no incentive may be given to favour the purchase or use of medicinal products.

"Price volume" agreements may be stipulated at a central level with the AIFA during negotiation of the reimbursement price of medicines when there is a multiplicity of MEA – Managed Entry Agreements (*cf.* question 4.7).

Purchases of medicinal products by public entities take place through public tenders and by law, the criterion will be the most economically advantageous offer, and it will be identified on the basis of the best quality/price *ratio* or based on price or cost. The economic offer generally provides for only the percentage discount applied with respect to the reserve price, valid for the entire presumed quantity of the supply, to be indicated. In cases where negotiation directly with the public entity is allowed, the company may make an offer with volume-related discounts. The offer must be made in writing.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

We refer back to question 4.5 on tenders for public supplies. Consistently with the criterion whereby the contract is awarded to the lowest price, the tender regulations generally provide that the final winning price be all-inclusive and also include the cost of any administration devices. Consequently, offers in cash or in kind to favour the purchase of medicinal procedures are not allowed. Consideration may be given to Patient Support Programmes, but at the moment these programmes are not a "measurable" factor in connection with offers for the purchase of medicines or negotiation of the price of medicines (see question 6.7).

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

"Payment by result", "risk sharing" or "cost sharing" agreements (MEAs) are very widespread and are drawn up by the company with the AIFA during negotiations on the reimbursability of the medicine. During negotiations, all the contractual conditions and (objective) criteria are set to establish when the medicinal product has not had the expected therapeutic response, and if there can be a refund. It is advisable that the company negotiate clearly refund timing and procedures and the overlaps with the pay-back system operating in Italy in relation to the fixed spending ceilings for sales to hospitals and the territory (e.g. pay-back or claw-back).

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Pharmaceutical companies may sponsor CME events. A special set of rules applies (State Regions Agreement of 2 February 2017 and Operating Manuals approved by the National Commission for Continuous Training – CNFC on 6 December 2018, in application of the State Regions Agreement) to ensure that HCP education is not influenced by parties with commercial interests in the healthcare sector. HCPs may acquire no more than ⅓ of their education requirement through recruitment (economic and other benefits such as hospitality, etc.) by the sponsor company. The regulations are very detailed, but the main principles are as follows:

- the pharmaceutical company may sponsor the CME event (exclusively or non-exclusively) with a specific written contract;
- the Sponsor may not select and/or indicate the tutors and the moderators and all relations with tutors and moderators (including economic relations) are mediated by the Provider, who must be an independent accredited third party;
- the name and logo of the Sponsor may appear only before the start and after the end of the event and on the last page of materials, leaflets and the event programme;
- the Sponsor may be involved in the distribution of promotional material for the event and may have no more than two of its representatives at the venue; and
- during the event, the active ingredient of medicinal products may be indicated, but the commercial name may not be indicated, even if it is not related to the topic under discussion.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

In addition to the criminal code which prosecutes corruption, the main rules designed to prevent the corruption of HCPs are contained

in the Code on Medicines and the Farmindustria Code. Many rules refer to relations between companies and HCPs in connection with promotional activities. The main rules are: no utility (gifts, donations) may be given to physicians to induce prescribing, except for items of negligible value, hospitality at conferences and congresses (which is strictly regulated); and collaboration (which must be justified, specified in writing, be remunerated at fair market value, the efficacy of the service must be demonstrated, there must be no conflicts of interest, and for employees of public entities the authorisation of the entity must be obtained).

To strengthen the preventive system, the Farmindustria Code has introduced rules on the publication of TOVs (a bill called the Sunshine Act was presented on 10 November 2018 and is currently under consideration by Parliament. The bill provides for the regulatory obligation to publish transfers greater than €10 made by pharmaceutical companies to HCPs and to HCOs, and introduces penalties for the omission of false or incomplete information, up to €200,000).

Pharmaceutical companies in Italy implement organisation models in accordance with Legislative Decree 231/2001, which introduced corporate liability for offences (including corruption, fraud to the detriment of the State, and others) committed by employees, managers and co-workers.

Enforcement of the rules on the promotion of medicinal products is the responsibility of the AIFA and/or the MOH, which, in the event of breaches, apply the envisaged administrative penalties; in cases where they believe a crime has been committed (e.g., corruption), they are required to inform the public prosecutor. Investigations of crimes of corruption may be initiated autonomously by the public prosecutor when it learns of criminal activity. The two authorities may conduct their activities in parallel.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Hospitality to HCPs for congresses and meetings sponsored by the pharmaceutical company is governed by art. 124.4 of the Code on Medicines. Prior AIFA approval is required and must be applied for 60 days before the date of the congress, with details of the meeting and a breakdown of planned expenditure attached to the application. The AIFA issues its opinion within 45 days of receipt of the application. Congresses organised directly or indirectly by the Italian company attended mainly by Italian physicians may not take place abroad. In any case, the laws and codes of conduct of the country hosting the event also apply. If the event is organised by the parent/by the local affiliate, the Italian company will be responsible for their arrangements for Italian physicians invited abroad. The law does not place thresholds on hospitality: the principle of sobriety applies. Expenditure thresholds and other conditions are set by the Farmindustria Code (*cf.* question 5.2).

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The company may offer hospitality for the congress (travel, accommodation and enrolment fees), but may not pay any form of compensation for his/her time.

Hospitality conditions: travel and hospitality expenses are limited to qualified HCPs and do not extend to persons accompanying them; hospitality may not extend beyond 12 hours before the start of the meeting or 12 hours after the end; and may not prevail on the technical-scientific purposes of the event. Art. 3 of the Farmindustria Code also sets expenditure ceilings: four-star hotel; €60 per meal; travel in economy class; business class only for speakers and moderators and for international events if the flight is more than six consecutive hours; and gala dinners or cultural events/tourism are not included. The same professional may not be invited more than twice a year.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

The pharmaceutical company is responsible for the contents of the meeting and its organisation, according to the details declared in the approval application. For events for which approval is not required, the company is nevertheless responsible for content and arrangements. Any breach of the Code on Medicines (including breaches reported by third parties) will be examined by the AIFA who has the right to prohibit the meeting from taking place. Severe rules apply in particular to CME events where the Provider is the main guarantor for compliance with the rules and for the scientific nature of the content (*cf.* question 4.8).

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

It is possible to pay HCPs to participate in advisory boards. The rules are the same as those that apply to collaboration (*cf.* question 2.7), based on the conditions of art. 4.1 of the Farmindustria Code. The advisory board must not be created to promote medicines or to induce prescribing of medicines. If the expert is a public-sector employee, the approval of the entity may be required for him/her to participate in the advisory board. In any case, the expert must have no incompatibilities or conflicts of interest in undertaking the engagement. It is advisable that the company implement appropriate SOPs with regard to advisory boards to ensure activities are transparent and documentable.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Direct financial agreements between the company and trial investigators are not allowed: the written agreement must be signed with the HCPs employer. Post-marketing surveillance studies are subject to the AIFA Guidelines of 20 March 2008. The Farmindustria Code (art. 4.4) refers to the AIFA Guidelines and set conditions for the execution of such studies: written contract between sponsors and participating bodies; protocol approved by the medical division of the company or by the scientific office; remuneration based on criteria of cost-effectiveness and fair market value; sales representatives may be involved only with logistic and non-negotiable questions; and any tools (e.g., tablets or smartphones should preferably be avoided) to be supplied only to the Institution and must be returned on completion of the study. The company is responsible even if it assigns execution of studies to third parties.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

As specific legislation neither exists in Italy nor at a regulatory or ethical level for MRs, reference is made to the EphMRA code (European Pharmaceutical Market Research Association). The fee is usually paid directly by the research agency appointed by the pharmaceutical company, and should be: dependent only on the correct completion of a questionnaire/interview and not on any additional conditions in the case of one-off surveys; kept to a minimum; appropriate to the time involved; no more than the fair market value for that individual's professional consultancy or advice; appropriate to the MR subject type; appropriate to the task(s); for patients/members of the public it is a token of appreciation – not a fee for time; and handled only by the Agency. However, if the market research is conducted by a company's in-house researchers, MR subjects' personal data must not be accessible to company personnel outside the research team.

The purpose of the consultancy of the HCP should be identified with respect to the justified needs of the company requesting assistance and to the absence of incompatibilities or conflicts of interest of the HCP in providing the service, also considering any public positions he/she holds. So while there are no prior preclusions on the purpose of the consultancy, in practice it must be considered in relation to parameters that ensure the activity is legitimate, and remembering that utilities may not be given to physicians for promotional purposes. In other words, the company must check that: the consultancy requirement is objective, real and justified, that the contribution of the consultant adds value and is pertinent to his/her experience and expertise; that the consideration is compatible with fair market value; and that the service is real and verifiable.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

OTC and SOP may be advertised to the general public after authorisation from the MOH (art. 118 Code on Medicines). Advertising must be transparent, favour rational use of the medicine, present it in an objective manner without exaggerating its properties and must not be misleading. It must provide the name of the medicine, information for correct use and an invitation to read the warnings. It must not have the content prohibited under art. 117 of the Code on Medicines (*cf.* art. 90 EU Dir/2001/83).

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

It is forbidden to advertise prescription-only medicines or medicines containing psychotropic or narcotic substances to the general public, although the MOH may authorise vaccination campaigns promoted by pharmaceutical companies (art. 115.2 Code on Medicines).

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are permitted to convey information about people's health or diseases, provided that there is no reference, direct or indirect, to a medicinal product (art. 113.2 Code on Medicines). Since there is no definition of "indirect mention", reference must be made to the (meagre) case-law on the question, which states that the mention of the medicinal product through the active ingredient constitutes a reference to the medicinal product, particularly when the product is the only one to contain that active ingredient. Disease awareness campaigns should be assessed on a case-by-case basis with regard to all the content they divulge and the other information present in the context in which they are presented (e.g., websites, Facebook pages). In this context it is possible to recommend that medical advice should be sought to prevent or treat a disease, but the names of physicians may not be given if the information comes from a pharmaceutical company.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

There are no laws regarding press releases. Public release of information on a medicinal product is accepted practice – including mention of the active ingredient or its name – solely for the purpose of announcing the medicine's authorisation and for a period strictly contiguous with the authorisation date, so that it is clear that the announcement via press release is only for informative and not promotional purposes. Any other situation should be assessed case-by-case (*cf.* also question 2.3).

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

In corporate brochures and Annual Reports, the company normally makes express mention of medicinal products, their dissemination and market positioning. In order for such information not to be considered as advertising, brochures and Annual Reports must address the parties concerned, not the general public. An activity is qualified as advertising not only by the medium used but also by the manner in which that medium is disseminated and the audiences reached. Content is significant too, and it is essential that the medicinal products (or active ingredients) be mentioned without over-detailed descriptions or claims about their properties.

Divulgence of general information about research and study is allowed provided that it has no promotional content or intention (if it publicises a study for the purpose of recruiting patients, the prior opinion of the Ethics Committee must be sought).

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

The relationship with patient organisations is governed only by self-regulatory rules. Under art. 4.6 of the Farmindustria Code, direct and indirect support as well as collaboration (including consultancy) is permitted, provided that: there is a written agreement setting out the amount and purpose of funding; use of the association logo and the procedures have had prior approval; sponsorship is transparent and is not for promotional purposes; for travel and hospitality, the regulations governing congresses apply; and the list of the patient organisations supported the previous year, with the purpose and amount of funding, is published on the company website (for the first three months of the year). Contracts for services to the company (also through representatives of the association acting as experts/consultants on advisory boards) are permitted only on projects in the interests of public health or research. In this case too, a written agreement is required detailing the services and remuneration, which must be transparent and in line with fair market value. No company may ask to be the exclusive sponsor of a patient organisation.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The law makes no restrictions, except for the prohibition on providing medicinal products (to the public). The question is not regulated by the Farmindustria Code. Nevertheless, the supply of items directly to or for the benefit of patients is not contemplated in order to avoid such action being regarded as an illegitimate form of advertising of medicines. Any items that may be needed are delivered through the bodies that assist patients. In Italy, Patient Support Programmes (PSP) to enhance compliance with innovative treatments are spreading, which may justify support for the benefit of the patient; nonetheless this is made available through the free decision of the physician or the body assisting the patient. Case-by-case assessment is advisable. It should also be remembered that privacy law does not allow companies to know the names of patients. The Farmindustria Code has introduced a new art. 4.7, which regulates PSPs by providing that the patient must be in treatment with a: previously authorised pharmaceutical product; that the PSP must ensure pharmacovigilance management; privacy management, responsibility for the management of materials, responsibility for labour law management and compliance; that the corporate function responsible for decision-making of the PSP must not be commercial and must operate with the supervision of the company's compliance function, that the data collected in the PSP must only be used for the purposes of supporting patients; while any use for other purposes must be separately contracted.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Parties funding a clinical trial in Europe are required to publish the results in EudraCT, the European database of clinical trials managed by the EMA and provide the public with a summary of the results of the trial. Since 2014 all trials must be published independently from the result. The EudraCT Register will be replaced by the database envisaged by Regulation EU 536/2014.

In Italy, the AIFA clinical research on drugs portal (PRC), which is currently being reorganised with the migration of the data of the national observatory on clinical trials (OsSC), is the source of public information on clinical trials conducted on medicines in the country. Finally, a register of observational studies (RSO) has been created to collect data on non-interventionist clinical research in a single national archive; it is not yet operational.

Also, in accordance with art. 5 of the Farmindustria Code, pharmaceutical companies will be required to publish aggregate annual spending on R&D work (clinical trials and prospective observational studies involving collection of patient data), as well as spending for Investigators Meetings, Advisory Boards or hospitality, when related to research activities.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no such requirement in law, self-regulatory rules apply (*cf.* question 4.9 and 7.3).

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Disclosure of Transfers of Value (TOV) made directly or indirectly for the benefit of HCPs, HCOs and Patient Organisations is set out in the Farmindustria Code (in accordance with the EFPIA Code). It is binding only for associates; for other companies, it represents a principle of best practice for the purpose of compliance. TOV data for each year is published within the first six months of the following year in the country where the beneficiary is domiciled, in accordance with the local self-regulatory code. If the company does not have an affiliate in the country where the beneficiary is

domiciled, the transferor company must publish the TOV data in accordance with the self-regulatory code of the country where the beneficiary is domiciled. The data to be published is as follows:

- for HCPs: expenditure for participation at conferences and congresses (enrolment, travel, hospitality, excluding meals and beverages) and remuneration for professional consultancy and services;
- for HCOs: donations and contributions (including bailments), in cash and in kind; direct or indirect funding at congresses, including enrolment fees or travel costs and hospitality for physicians; professional consultancy; and services as shown in a written contract;
- for patient associations (*cf.* question 6.6); and
- data on OTC medicines, for promotional material of negligible value, meals, beverages and samples are not published.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

While companies must make every possible effort to obtain the consent of HCPs (art. 5.5 Farmindustria Code), if consent is not forthcoming, data is published in aggregate form according to the following criteria:

- number of recipients (absolute value and as a percentage of the total);
- aggregate figure for HCPs; and
- aggregate TOVs as a percentage of total TOVs.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

This topic is regulated by the MOH guidelines of 17 February 2010, supplemented on 6 February 2017, 25 July 2017 and 25 July 2018, which distinguish between advertising to the general public and to HCPs.

For advertising to the general public, the publication of web pages or banners, pop-up or overlay frames, and all other forms of presentation on the internet is to be considered, to all intents and purposes, as advertising, given that they have had prior approval by the MOH. Approval is not required for institutional advertising, i.e., advertising that promotes the company image and/or logo, possibly accompanied by the list of marketed products, together with images of their packaging and leaflets, in the absence of any healthcare claim.

For advertising to HCPs, access to an internet site must be restricted through encrypted areas, access to which is enabled with a password issued after transmission of the data needed to identify the HCP user.

The Farmindustria Code provides that every internet site created by an Italian company or a company that operates in Italy which addresses the public and HCPs must clearly indicate the sponsor, the source of the information on the site, the recipients and the site objectives.

Advertising on internet sites is controlled not only by the pre-clearance regime described above, but also by the competent authorities. In Italy, special arms of the Carabinieri, the NAS anti-sophistication units and the Postal Police verify activities on the internet and have in the past blocked unlawful activities, including advertising, by reporting them to the authorities.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

The area dedicated to HCPs must be encrypted to ensure that access is reserved for them; on sites to which the public has access, the links to areas providing information for HCPs must act as barriers blocking access for all other parties.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Advertising on independent sites is allowed subject to the receipt of MOH approval by the party promoting the product, irrespective of the site on which the advertisement appears.

In the case of links from sites (and also banners or other frames) which in turn contain advertising material, the above-mentioned guidelines distinguish between authorised advertising or advertising not subject to approval or non-authorised advertising, and provide that:

- links are acceptable between sites that both contain authorised promotional material on condition that the company responsible for the material on the internet employs a disclaimer for the user "*You are leaving the XXX company website containing authorised promotional material pursuant to the current laws governing healthcare advertising*";
- links are acceptable from a site containing authorised promotional materials to another site not containing promotional material subject to authorisation (e.g., containing information on healthcare education) provided that the user is alerted with a message as above; and
- links are not acceptable from a site containing authorised promotional material to another site containing promotional material subject to authorisation that has not been authorised.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

In addition to advertising for non-prescription medicines with prior MOH authorisation, the company may divulge the following information, which does not require prior authorisation since it is not subject to the provisions governing advertising:

- the information shown on the label and/or leaflet of the medicinal product (which have already received specific authorisation);
- sales catalogues and product price lists (provided that information about the medicine does not appear); and
- information relating to people's health or to diseases, provided there is no direct or indirect reference to a medicinal product (disease awareness).

The MOH guidelines of 6 February 2017 permit advertising, without prior MOH authorisation, of the list of non-prescription and OTC medicinal products, whose names provide an activatable link exclusively to the leaflet and possibly to an image of the package. In this context, no message relating to the healthcare properties of the SOP medicine may be visible, otherwise authorisation is necessary.

Italy applies the principle established by the ECJ (C-316/09) whereby information on prescription medicines may be published on an internet site accessible to the public on condition that such information is accessible exclusively to people who wish to obtain it (so-called "pull" system), with the exclusion of any so-called "push" activity, and that it consists solely of the faithful reproduction of the package of the authorised medicinal product and the literal and full reproduction of the leaflet or summary of SOP product characteristics approved by the authorities.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

The use of social media by pharmaceutical companies to advertise non-prescription and OTC medicines is governed by the recent MOH guidelines of 6 February 2017, 25 July 2017 and 25 July 2018, which adopt a more open approach than previously allowed even though there were no express prohibitions.

The guidelines allow the use of the main and most widespread social media (Facebook, Instagram and YouTube), but envisage restrictions to limit the use of interactive functions (e.g., likes, counter, comments, content sharing, etc.). The reason for this is the need to ensure that advertisements approved by the MOH are static by avoiding changes or alterations arising from typical "social" activities. The MOH believes that any "change", such as the addition of comments, advice, user recommendations, would undermine control of the advertisement for protection of consumer health. To summarise:

- **Facebook**: an advertising post (with authorisation) may be published on the right-hand column of the so-called "wall"; an advertisement may be published directly on the wall on condition that the "comments" and "like" functions are deactivated. Since the "share" function cannot be deactivated, the MOH requires all advertisements to contain a disclaimer which attributes responsibility for sharing to the user.
- **YouTube**: authorised advertisements may be published provided that interactive functions are deactivated. Likes or dislikes may be expressed, but the number cannot be viewed; the video may be shared, but only in the YouTube watch page, even if sharing takes place with the "share" button or through a copy-paste of the URL (this guarantees the staticity of the advertisement). Authorised videos may be reproduced in pre-roll mode, i.e., before the videos are searched for by the user.
- **Instagram**: authorised advertising images or short videos may be published in the "Story" section, where users viewing these images/videos are not able to post comments, express reactions or share them.
- **Twitter**: use of Twitter is currently not permitted, because it does not allow the minimum content of public advertising of medicinal products to be transmitted to the recipient in a single tweet.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The main development is the MOH guidelines on use of digital and social media in advertising non-prescription medicines of 6 February 2017, 25 July 2017 and 25 July 2018, and the corresponding guidelines of 20 December 2017 on the advertising of medical devices.

Although only partially evaluable as a reference for pharmaceutical advertising, we recommend viewing the Digital Chart issued by the Istituto di Autodisciplina Pubblicitaria (IAP) for new forms of commercial communication created with digital technology (available on the website www.iap.it) as an expression of best practices for compliance during the proper production of advertising.

In the area of case law, attention is drawn to Council of State decision no. 2217 of 12 May 2017, which overrode a distinction operating in Italy between OTC medicines and SOP, thus making it possible to advertise SOPs too (previously this was not allowed by the MOH) and bringing Italy into line with European law, which does not make this distinction and prohibits advertising to the public only of prescription medicines.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The AIFA guidelines on advertising of medicinal products to HCPs are currently being finalised. These guidelines will provide additional important operating indications.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The last year has certainly seen a consolidation and indeed a strengthening of the trend in the pharmaceutical sector to adopt organisation and control models designed to prevent offences, especially offences committed in relations between companies, and HCPs and HCOs.

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Astolfi e Associati Studio Legale was founded by Antonio Astolfi in 1955. Fostering his original interest in international trade law he founded the law journal *Diritto comunitario e degli scambi internazionali* (EU law and international trade law). Later, in the Sixties, he developed a strong interest in pharmaceutical and health law (life sciences) showing a longsighted vision. In 1968, he founded the law journal *Rassegna di diritto farmaceutico* (Pharmaceutical law) still edited today, after more than 40 years, in its new version of *Rassegna di diritto farmaceutico e della salute*. This heritage is today the practice area of Astolfi e Associati, deployed from civil, labour, commercial and banking law to pharmaceutical, health and food law, proposing complementary and comprehensive services to clients to fully meet their needs for legal advice.

Astolfi e Associati advise Italian and foreign clients in both extrajudicial and judicial matters.

# Japan

Somuku Iimura

Yoko Kasai

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

In Japan, the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Law No. 145 of August 10, 1960, as amended) (the "Pharmaceutical Affairs Act") governs the advertising of medicinal products. In connection with the regulations on medicinal product advertising under the Pharmaceutical Affairs Act, the Standards for Fair Advertising Practices concerning Medicinal Products (Notice No. 0929-04 of September 29, 2017) (the "Standards for Fair Advertising Practices") issued by the Director-General of the Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labour and Welfare (the "MHLW") provide certain rules prohibiting false or excessive advertising. In addition, the Guidelines on Information Provision in connection with Promotional Activities for Ethical Drugs issued recently by the MHLW (Notice No. 0925-01 of September 25, 2018) (the "Guidelines on Information Provision") provide certain rules for the provision of information for ethical drug promotional activities to be complied with by pharmaceutical companies.

There are also industry-level self-regulating codes of practice on promotional activities for medicinal products, including the Code of Practice for the Promotion of Ethical Drugs (the "Code of Practice") established in 2013 by the Japan Pharmaceutical Manufacturers Association (the "JPMA").

With respect to benefits and premium offers for the promotion of ethical drugs, the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry (the "FTC-EDMI") established the Fair Competition Code concerning Restriction on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry (the "Fair Competition Code"), along with several guidelines for benefits and premium offers and contributions to medical institutions. The Fair Competition Code is a specific adaptation for the pharmaceutical industry of general rules under the Act against Unjustifiable Premiums and Misleading Representations (Law No. 134 of May 15, 1962, as amended), which prohibits the inducement of customers by unjustifiable premiums to ensure fair competition. The Fair Competition Code was established upon certification by the Japan Fair Trade Commission (the "JFTC") and the Consumer Affairs Agency (the "CAA").

### 1.2 How is "advertising" defined?

According to Notice No. 148 of September 29, 1998, issued by the Pharmaceutical Safety Bureau of the former MHLW, "advertising" subject to the Pharmaceutical Affairs Act is defined as that which fulfils all of the following conditions:

(a) clearly intended to induce consumers to purchase products;

(b) specifies the names of particular medicinal products; and

(c) is capable of being viewed by the public.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The Pharmaceutical Affairs Act does not provide any specific requirements for pharmaceutical companies to implement particular arrangements to ensure compliance with the various laws and codes of practice on advertising. However, in practice, pharmaceutical companies usually have in place their own verification procedures for advertising medicinal products, to comply with applicable laws and codes of practice. In this regard, the Code of Practice provides that member companies of the JPMA must appoint a manager in charge of validating promotional materials and establish certain in-house verification procedures for advertising.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

In connection with the provision of information for ethical drug promotional activities, the Guidelines on Information Provision require pharmaceutical companies to have SOPs to be followed by their employees in the course of information provision in their promotional activities for ethical drugs.

Despite the Guidelines on Information Provision, as described in question 1.3, pharmaceutical companies usually adopt in-house verification procedures to ensure that the contents of their advertisements comply with legal requirements.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

The Pharmaceutical Affairs Act does not require prior approval by a regulatory or industry authority to advertise medicinal products. However, a pharmaceutical company still has the option to consult with a regulatory or industry authority regarding the advertising before use, in order to confirm whether the advertising complies with applicable laws or codes of practice.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The Pharmaceutical Affairs Act does not explicitly provide that the regulatory authorities have the power to stop further publication of such advertisements nor to insist on the issue of a corrective statement; however, when the advertisement is in breach of the Pharmaceutical Affairs Act, and the authority finds that it is necessary to prevent the occurrence or spread of hazards to public health, the MHLW may order the pharmaceutical company to take necessary measures to improve operations, which include taking corrective and preventive action on the validation process of its advertising. The regulatory authority also has the power to rescind the company's pharmaceutical business licence or order the suspension of all or part of the business operations for a given period if it finds that the company's advertising violates the Pharmaceutical Affairs Act. Companies have the right to appeal these dispositions by the regulatory authorities under the Administrative Appeals Act (Law No. 160 of September 15, 1962, as amended).

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Failure to comply with the rules governing the advertising of medicines under the Pharmaceutical Affairs Act is subject to criminal sanctions, which will be imprisonment with work for not more than two years or a fine not exceeding two million yen, or both (Article 85 of the Pharmaceutical Affairs Act). As described in question 1.6, the MHLW strictly enforces the rules on the advertising of medicines under the Pharmaceutical Affairs Act through administrative action, which includes issuing an order to take necessary measures to improve the company's operations. There are a number of cases where the competent authorities ordered the pharmaceutical company to take necessary measures to improve their advertising-related operations. Such administrative action along with a public announcement would have a significant adverse impact on that company's business reputation.

If a company fails to comply with the rules on promotional activities of medicines under the Fair Competition Code, it will be subject to a penalty imposed by the FTC-EDMI. If the FTC-EDMI finds that the pharmaceutical company violates the Fair Competition Code, the FTC-EDMI may issue a warning letter to the company claiming that the company should take necessary action to correct the violations identified. Further, if the FTC-EDMI finds that the company still violates the Fair Competition Code after receiving such warning letter, the FTC-EDMI may impose a monetary penalty of not more than one million yen; exclude such company from the FTC-EDMI; or ask the CAA to take necessary administrative action against the company.

Direct action through the courts in relation to the advertising infringement in the Pharmaceutical Affairs Act that competitors can take through the courts is limited. As described in question 1.9, if the advertising includes false allegations that could harm the business reputation of a competitor, the competitor may seek an injunction suspending such advertising under the Unfair Competition Prevention Act (Law No. 47 of May 19, 1993, as amended).

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The MHLW and/or the competent prefectural government is responsible for the supervision and enforcement of the pharmaceutical advertising rules under the Pharmaceutical Affairs Act. In practice, such competent authorities may investigate matters regarding the Pharmaceutical Affairs Act, even though the self-regulatory body of the JPMA already having assessed such matters has rendered a decision in accordance with the Code of Practice.

Similarly, the FTC-EDMI is responsible for the supervision of the Fair Competition Code, and it may investigate its member company to assess whether its promotional activities comply with the Fair Competition Code, and render a decision to such member company. The CAA and/or the JFTC, which are the competent authorities responsible for the enforcement of the Act against Unjustifiable Premiums and Misleading Representations, may also investigate matters based on the assessment by the FTC-EDMI and render a decision to the subject company.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Under the Unfair Competition Prevention Act, a person whose business interests have been infringed or are likely to be infringed by "unfair competition" may seek an injunction suspending or preventing the infringement against the person that infringed or is likely to infringe such business interests. In relation to advertising, for example, announcement or dissemination of a falsehood that may damage the business reputation of a competitor constitutes "unfair competition" under the Unfair Competition Prevention Act. In addition, any act that falls under the definition of "unfair trade practices" is prohibited under the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (Law No. 54 of April 14, 1947, as amended) and related guidelines issued by the JFTC; however, there is no specific regulation focusing on pharmaceutical advertising under this Act.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Under the Pharmaceutical Affairs Act, advertising regarding the name, manufacturing process or indications and effects of an unauthorised medicinal product is strictly prohibited.

Although the Pharmaceutical Affairs Act does not explicitly exclude certain forms of exchange of scientific information on such medicines at scientific meetings, in the commentary on the Code of Practice, the JPMA commented that this prohibition on the advertising of unauthorised medicinal products should not be intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress and that this prohibition should not be intended to restrict the following types of information provision:

(a) the full and proper exchange of scientific information about a drug (for example, the presentation of research findings in a meeting of any academic society or in a scientific journal);

(b) the display of scientific exhibition materials about an unapproved drug in accordance with separate guidelines at an international scientific conference, on condition that the subject drug has been approved by another country;

(c) the supply of peer-reviewed scientific literature upon the request of a doctor; or

(d) the disclosure of information regarding products under development to a company's shareholders, as may be required under laws and regulations.

However, according to the commentary on the Code of Practice, the provision of information on unauthorised drugs in a seminar sponsored by a pharmaceutical company is prohibited.

In addition, under the Guidelines on Information Provision, upon the request of healthcare professionals, the provision of information on unapproved drugs, off-label drugs, or dosage and administration that are not approved in Japan is permissible only if all of the following conditions are met:

(a) such information should be provided separately from the other information provision activities for the promotion of ethical drugs;

(b) the information to be provided should be limited to that requested by the healthcare professionals and should be provided only to the healthcare professionals who made the request;

(c) pharmaceutical companies must not purport to have received a request from healthcare professionals despite no such request having been made;

(d) the information to be provided must not contain false or exaggerated statements, should be accurate and supported by scientific and objective evidence, and must not be summarised, incomplete or exaggerated;

(e) when providing test results or papers regarding research in which pharmaceutical companies are involved, such research should be properly managed in accordance with the "Ministerial Ordinance Concerning Standards for Implementation of Clinical Trials for Medical Drugs" (Ministry of Health and Welfare Ordinance No. 28 of 1997), the "Clinical Research Act" (Act No. 16 of 2017) or regulations equivalent thereto;

(f) negative information, such as the increased risk of adverse reactions and the fact that no significant difference has been proven by clinical trials, should also be provided in a proper manner;

(g) the fact that the efficacy and effect (indication), dosage and administration of the ethical drug with respect to which information is to be provided have not been approved should be clearly explained; and

(h) the details of the information provision, such as the background, recipients, and content of the information to be provided, should be recorded and such records should be retained.

The provision of off-label information is also subject to the same restrictions on the advertising of unapproved drugs under the Pharmaceutical Affairs Act.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Under the Pharmaceutical Affairs Act, information on unauthorised medicines and/or off-label information must not be published for promotional purposes, as described in question 2.1.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Issuing press releases about unauthorised medicines and/or off-label information for promotional purposes is prohibited under the Pharmaceutical Affairs Act. However, as described in question 2.1, if such press releases are not intended to promote a specific medicinal product and are required in order to inform shareholders of product development as a part of a company's financial information, it could be argued that such press releases should not be considered advertising of unauthorised medicines. Whether or not the information provided via press releases could be deemed information intended to promote specific medicinal products to the public depends on the case, the specific contents of the information should be carefully reviewed prior to issuing the press releases.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

As described in question 2.1, such information must not be sent to healthcare professionals under the Pharmaceutical Affairs Act.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The principles of the ECJ judgment have not been incorporated into legislation or practical guidance in Japan.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Such provision of information on unauthorised medicines or indications to healthcare institutions may be considered the promotion of unauthorised medicines or indications prohibited under the Pharmaceutical Affairs Act.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

There are no specific guidelines that have been issued on market research exercises concerning possible launch materials for unauthorised medicinal products or indications. However, if such market research involving healthcare professionals is conducted for the purpose of promoting specific unauthorised medicinal products or indications, it would be deemed prohibited advertising of unauthorised medicinal products under the Pharmaceutical Affairs Act.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The Pharmaceutical Affairs Act does not specify the information that must appear in advertisements directed to healthcare professionals. The JPMA provides the list of information to be included in advertisements directed to healthcare professionals in the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information: name of the product (both brand name and generic name); therapeutic category; regulatory classification; indications and usage; dosage and administration; warnings and precautions; presence or absence of listing on the National Health Insurance price list; name of the marketing authorisation holder with a contact address; information concerning the limit on the prescription period (if any); conditions on marketing authorisation (if any); and preparation date of the advertisement.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

As described in question 2.1, advertisements of unauthorised medicinal products are prohibited (Article 68 of the Pharmaceutical Affairs Act). Also, the advertising of medicinal products must not be false or exaggerated in relation to the name, method of manufacturing or indications or effects (Article 66 of the Pharmaceutical Affairs Act). Furthermore, the Standards for Fair Advertising Practices prohibit the advertising of prescription-only medicinal products to the general public. As described in question 3.1, advertisements to healthcare professionals must comply with the rules provided in the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information.

There are no particular restrictions that prohibit the provision of advertisements that refer to studies not mentioned in the SmPC. However, if studies are referred to in advertisements, the description of such studies should not contradict the studies mentioned in the SmPC. The data of the studies included in the advertisements must be accurate, credible, and supported by scientific evidence.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

The Pharmaceutical Affairs Act prohibits advertisements that could be misunderstood as indicating that healthcare professionals have guaranteed the indications and effects or properties/performance of the subject medicinal products (Article 66, paragraph 2 of the Pharmaceutical Affairs Act). Specifically, the Standards for Fair Advertising Practices prohibit the advertising of medicinal products, which includes endorsements, recommendations, or testimonials by healthcare professionals.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There is no explicit requirement that there should be data in any "head to head" clinical trials before comparative claims may be made in the advertisement of medicinal products.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Advertisements that may disparage different medicinal products or competitors are prohibited under the Code of Practice. The Code of Practice also provides that any comparison made between different medicinal products should be capable of substantiation, and the brand names of comparative drugs must not be included in comparative advertisements. The JPMA provides certain rules on comparative advertisements of medicinal products in the Guidelines for Preparation of Outline of Prescription Pharmaceutical Product Information. For example, commentary regarding the efficacy and safety of comparative drugs should not be included when results of a clinical comparative study are placed in advertisements. Furthermore, referring to a competitor's product or indication that has not yet been authorised in comparative advertisements is not allowed. In this connection, the Guidelines on Information Provision also prohibit pharmaceutical companies from disparaging other companies' products to assert the superiority of their own products.

In addition, general rules on comparative advertisements under the Act against Unjustifiable Premiums and Misleading Representations also apply to comparative advertisements of medicinal products. The JFTC provides guidelines on comparative advertisements, and advertisements which include the following comparisons are deemed impermissible:

(a) comparison by indicating information that is not substantiated and which is incapable of being substantiated;

(b) comparison based on unfair grounds, such as an emphasis on the importance of issues that are inconsequential to the selection of products by consumers, or an arbitrary selection of the products compared; or

(c) advertisements disparaging another company and/or its products.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The distribution of scientific papers at the request of healthcare professionals is allowed under the Code of Practice. Also, the information provision of general scientific information to healthcare professionals is not restricted by the regulations on the premium offer under the Fair Competition Code, unless it improperly influences transactions with healthcare professionals. However, if the distribution of scientific papers and/or proceedings of congress is designed to promote a specific medicinal product of the company, such activities could be considered as advertising or an improper offer of a gift or economic benefit, and thus subject to regulations under the Pharmaceutical Affairs Act and the Fair Competition Code.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There are no particular regulations on "teaser" advertisements for medicinal products. In this connection, the Code of Practice provides that advertisements which are mainly composed of the names of medicinal products must be accompanied by certain product information (i.e., therapeutic category, regulatory classification, generic name and presence or absence of listing on the National Health Insurance price list), as well as the contact address for further information. In addition, such advertisements must not include information concerning the safety or effectiveness of the given product (e.g., indications and usage, dosage and administration, and warnings and precautions) and must clearly indicate that such information should be referred to in the package insert of the product.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Under the marketing authorisation and SmPC regulations under the Pharmaceutical Affairs Act, there are no applicable cases where Product A would be authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A. If combination use of Product A and Product B for a particular indication is approved by the regulatory authority, either the SmPC of Product A or Product B must include that indication, so an off-label information provision would not happen both for Product A and Product B in that case.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Samples of medicinal products may be provided to healthcare professionals with their product information, only after a pharmaceutical company obtains marketing authorisation for such medicinal product. A pharmaceutical company must comply with the detailed requirements for the provision of samples of medicinal products, which are provided under the Fair Competition Code. The Code of Practice also notes that the quantity of samples to be supplied to healthcare professionals should be limited to the minimum for evaluation.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Under the Fair Competition Code, offerings of gifts or economic benefits to healthcare professionals in a manner likely to improperly induce the transactions of medicinal products are prohibited; however, a pharmaceutical company is permitted to offer gifts or economic benefits that are considered "discounts" or "after-sales service" for the subject medicinal products in light of normal business practices.

The Code of Practice provides that a pharmaceutical company must not give gifts or other items which may improperly influence the use of medicinal products or which may detrimentally affect the reputation of medicinal products.

In connection with this, the commentary of the Code of Practice provides, among others, that (i) gifts for personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of healthcare professionals (either directly or through clinics and institutions) are prohibited, and (ii) providing or offering a promotional aid (a non-monetary item given for promotional purposes) to healthcare professionals in relation to the promotion of prescription-only medicines is prohibited (this will not apply to pens and notepads provided to healthcare professionals in the context of company-organised events for the purpose of taking notes during a meeting), as provided in IFPMA's Code of Practices (2019 edition).

Furthermore, inappropriate gifts or donations of money to a healthcare professional who works in the public sector (e.g., a national university hospital) may be considered bribes punishable under the Penal Code (Law No. 45 of April 24, 1907, as amended) and/or under the National Public Service Ethics Act (Law No. 129 of August 13, 1999, as amended).

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

The regulations on the offering of gifts or donations of money listed in question 4.2 also apply to healthcare organisations such as hospitals. The Fair Competition Code provides guidelines on the

donations to medical institutions. For example, under certain conditions, a pharmaceutical company can donate money to university hospitals for education and research purposes. However, donation equipment or money for the purpose of taking over the debts or expenses that should be paid by the medical institutions during the course of its normal practice (such as the cost of a nurse) is restricted under the Fair Competition Code.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The Fair Competition Code prohibits the offering of goods and services by a pharmaceutical company to healthcare professionals that might influence the prescription or therapeutic decisions by healthcare professionals. However, under certain conditions provided in the Fair Competition Code, it is permissible to provide goods or services that are necessary for the use of the company's medicinal product, or goods or services that could enhance the utility or benefit of the subject product. As a matter of course, such goods or services should not influence prescribing patterns by healthcare professionals.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Under the Fair Competition Code, economic benefits that are deemed to be discounts in light of normal business practices are not restricted as premium offers. In practice, medical institutions are usually provided medicinal products from wholesalers and not directly from pharmaceutical companies. In that case, pharmaceutical companies must not offer excessive or discretionary discounts that could lead to a restriction on wholesalers' business operations, including retail pricing, sales of competing goods, and the scope of the sales territory.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

As described in question 4.4, under certain conditions provided under the Fair Competition Code, it is permissible to offer to provide, or to pay for, additional medical or technical services or equipment, provided that such offer must be limited to the extent that offers of goods or services are necessary in order to use the subject medicinal products in medical institutions. The Fair Competition Code does not provide specific restrictions on package deals; however, it should be carefully reviewed whether such package deals could constitute "discounts" or "after-sales services" for the subject medicinal products in light of normal business practices, which are exempt from the offering of gifts and financial incentives regulated by the Fair Competition Code (see question 4.2).

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

There are no specific rules for a refund scheme where the medicinal product does not work. However, such a refund scheme may be considered a promotion representing assurances of the effectiveness and safety of a product, in which case it would be prohibited under the Pharmaceutical Affairs Act. In terms of prescription-only medicine, however, it is uncommon for pharmaceutical companies to sell prescription-only medicine directly to hospitals (i.e., a pharmaceutical company, which holds marketing authorisation for a medicine, sells the medicine to distributors, and then those distributors sell it to hospitals). Therefore, such a refund scheme for prescription-only medicine is unlikely to occur in practice.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

As described in question 4.2, under certain conditions provided in the Fair Competition Code, pharmaceutical companies may sponsor continuing medical education for healthcare professionals. Such sponsorship should not improperly influence the prescription or therapeutic decisions by healthcare professionals.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

As described in question 4.2, improper gifts or benefits provided to healthcare professionals who work in the public sector may be considered bribery punishable under the Penal Code or the National Public Service Ethics Act. The National Police Agency and the Public Prosecutors Office are responsible for the supervision and enforcement of the anti-bribery/anti-corruption regulations. In practice, the competent anti-bribery authorities may investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, regarding which the MHLW or the JPMA already assessed a breach of the pharmaceutical advertising rules, including the Pharmaceutical Affairs Act.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The Fair Competition Code, along with the hospitality guidelines, provides the rules on the offering of hospitality to healthcare professionals. The Fair Competition Code prohibits the offering of hospitality to healthcare professionals in a manner likely to improperly influence the medicinal product deal with healthcare professionals. This restriction does not, however, preclude the offering of hospitality to healthcare professionals that is offered along with certain gatherings hosted by pharmaceutical companies as a customary practice, as long as such offering is not extravagant or excessive in common-sense terms. As part of the hospitality guidelines, the FTC-EDMI provides certain conditions and a threshold on the costs of meals provided to healthcare professionals. Under these guidelines, for example, a pharmaceutical company is allowed to provide meals to a guest healthcare professional for up to 20,000 yen at an after-party of the symposia, conferences, and other meetings concerning the company's product.

The Code of Practice also states that the offering of hospitality to healthcare professionals during the events sponsored by the company should be moderate and reasonable. Furthermore, improper hospitality provided to healthcare professionals who work in the public sector may be considered bribes punishable under the Penal Code or the National Public Service Ethics Act.

The above rules also apply even if the hospitality offered to those professionals takes place in another country. There are no particular requirements that the arrangements should be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality is provided.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The Fair Competition Code does not preclude the payment for travel and accommodation fees to a healthcare professional in connection with attending a meeting for the presentation of the company's medicinal product. The pharmaceutical company may also pay the lecture fee and expenses to a healthcare professional attending such a meeting as a chairperson, guest speaker, or presenter.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

If a pharmaceutical company directly sponsors or organises a scientific meeting, the company is responsible for ensuring that the content and hospitality arrangements comply with the applicable regulations on promotional activities, including the Pharmaceutical Affairs Act, the Code of Practice, and the Fair Competition Code. Further, even where a pharmaceutical company organises a scientific meeting with the help of an independent third party, the company remains responsible for compliance with those applicable laws and regulations on the content and hospitality arrangements for the meeting.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

The Fair Competition Code does not preclude the payment to healthcare professionals for expert services in connection with post-marketing surveillance studies of the medicinal product, clinical studies, and other scientific studies. The Fair Competition Code provides detailed requirements for such payment, and non-compliance with such requirements may be considered improper inducement of purchasing or prescribing the company's product.

The Code of Practice provides that healthcare professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangement which covers these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

(a) a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;

(b) a legitimate need for the services must be clearly identified and documented in advance;

(c) the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the services;

(d) the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;

(e) the hiring of the consultants to provide the relevant services must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and

(f) the compensation for the services must be reasonable and reflect the fair market value. The compensation arrangement may include reimbursement of reasonable expenses, including travel, meals and accommodation.

In addition, as described in question 2.1, advertising of a pre-approval medicinal product is strictly prohibited, the engagement of the healthcare professionals in advisory boards should be carefully examined to determine whether it conflicts with such advertising restriction before entering into a service agreement with healthcare professionals.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

As described in question 5.4, a pharmaceutical company can pay healthcare professionals reasonable fees and expenses for post-marketing surveillance studies. The Fair Competition Code provides detailed guidelines on the payment for post-marketing surveillance studies to healthcare professionals.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

A pharmaceutical company can pay healthcare professionals reasonable fees and expenses for their participation in market research, if the company meets certain standards on the payment for market research under the Fair Competition Code.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Non-prescription medicines may be advertised to the general public. Such advertisement relating to non-prescription medicines is also subject to the restrictions on pharmaceutical advertising under the Pharmaceutical Affairs Act and the Standards for Fair Advertising Practices. It must not be a false or exaggerated advertisement in relation to the name, method of manufacturing or indications or effects of the non-prescription medicines; and it should not include any statements that could mislead the general public that a healthcare professional has certified the efficacy and effects of the non-prescription medicines.

As a self-regulatory code for advertisements of non-prescription medicines, the Japan Self-Medication Industry provides the Guidelines for Fair Advertising Practices of OTC drugs.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

The Standards for Fair Advertising Practices clearly prohibit advertisements of prescription-only medicines to the general public.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Under the definition of "advertising" (see question 1.2), a disease awareness campaign (not mentioning the name of a specific product) would not be considered advertising subject to regulations under the Pharmaceutical Affairs Act. However, a disease awareness campaign might be argued to be advertising in cases where only a specific prescription-only medicine exists for the treatment of the subject disease. In that case, such disease awareness campaign for the general public could be prohibited as an advertisement of prescription-only medicine.

In this regard, disease awareness campaigns regarding the target diseases of specific prescription-only medicines are subject to the Guidelines on Information Provision, and it is prohibited to recommend only treatment with a specific product or cause the general public to misunderstand that there are no means of treatment other than that with the specific product in the course of a disease awareness campaign. It is advisable that pharmaceutical companies consult with the relevant regulatory authority before launching disease awareness campaigns.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

The Standards for Fair Advertising Practices prohibit the distribution of product information concerning prescription-only medicines to the general public for advertisement purposes. As issuing a press release concerning prescription-only medicines to non-scientific journals could be deemed part of promotional activities, it is likely to be considered advertising of prescription-only medicines to the general public, which is prohibited.

As described in question 2.1, even though the advertising of unauthorised medicines or unauthorised indications is prohibited under the Pharmaceutical Affairs Act, the Code of Practice does not preclude the disclosure of information regarding the development of medicinal products to a company's shareholders. If a company issues press releases referring to the development of unauthorised medicines or unauthorised indications, such press releases should contain only objective information relating to the development of the products and should not have any advertising or promotional effect on the subject products.

As described in question 2.3, if the contents of a press release are deemed as being intended to promote specific prescription-only medicines, such press release would be subject to the regulations on the advertising of unauthorised medicines or unauthorised indications under the Pharmaceutical Affairs Act, so the contents of press releases referring to the development of unauthorised medicines or unauthorised indications should be carefully reviewed in advance.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

If the description of products and research initiatives in corporate brochures/annual reports is designed to promote particular products and falls within the definition of "advertising" described in question 1.2, the advertising regulations on medicinal products under the Pharmaceutical Affairs Act will also apply.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There is no specific legislation which governs the meetings between pharmaceutical companies and patient organisations, nor funding to patient organisations. However, as described in question 7.3, the JPMA has established a self-regulatory code for member companies to make publicly available information on donations, grants, benefits in kind or any other support provided by them to patient organisations. These guidelines recommend that member companies make publicly available information on their financial contributions to patient support organisations for the previous fiscal year through their websites. The information to be disclosed includes contributions to patient organisations' meeting costs, grants for supporting patient organisations, payments for writing articles, and payments for information that member companies have provided to patient organisations.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

As advertising of prescription-only medicines to the general public is prohibited as described in question 6.2, a pharmaceutical company shall not offer gifts or benefits to the patients in exchange for use of prescription-only medicines. As for non-prescription medicines, a pharmaceutical company is allowed to provide gifts or benefits to patients in exchange for purchasing the product or as a part of the promotion of the product, as long as such offering of gifts or benefits complies with the general restrictions on premium offers under the Act against Unjustifiable Premiums and Misleading Representations. The offering of gifts or benefits to the patients should not be: excessive leading to overconsumption; or abuse of non-prescription medicines by the patients.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

With respect to clinical trials that are required for applications for marketing authorisations of medicinal products under the Pharmaceutical Affairs Act, there is no statutory obligation for companies to disclose details of ongoing or completed clinical trials to the public.

However, the JPMA provides self-regulatory guidelines concerning the disclosure of clinical trial information via clinical trial registries and clinical trial results databases as outlined below:

(a) *Clinical Trial Registries*. A clinical trial registry serves as a repository for information on ongoing clinical trials. All confirmatory clinical trials and all exploratory efficacy trials (other than phase 1 trials) should be submitted for listing no later than 21 days after the initiation of patient enrolment. Such registration of clinical trials on any one of a number of free, publicly accessible, Internet-based registries should achieve the intended objectives. The registry should include the following information: brief title; trial description in lay terminology; trial phase; trial type (e.g., interventional); trial status; trial purpose (e.g., treatment, diagnosis, prevention); intervention type (e.g., medicinal product, vaccine); condition or disease; key eligible criteria, including gender and age; the location of the trial; contact information; and ingredient name or code of the investigational product.

(b) *Clinical Trial Results Databases*. A clinical trial results database serves as a repository for the summary results of completed clinical trials. The results of all confirmatory clinical trials and all exploratory efficacy trials conducted on a medicinal product that has been approved for marketing and is commercially available in at least one country should be publicly disclosed, regardless of the outcome. The results should be posted no later than one year after trial completion. Publication of clinical trial results in any free, publicly accessible Internet-based clinical trials databases (for example, the Japan Pharmaceutical Information Center database) should achieve the intended objectives.

On the other hand, with respect to clinical research (excluding clinical trials regulated under the Pharmaceutical Affairs Act), the Clinical Research Act (Law No. 16 of 2017), which came into effect on April 1, 2018, imposes a certain disclosure requirement on the manufacturers of medicinal products. The clinical research subject to such disclosure requirement is: (i) clinical research sponsored by manufacturers of medicinal products and clinical research related to the medicinal products of those companies; and (ii) clinical research studying medicinal products that have not been approved under the Pharmaceutical Affairs Act or off-label uses of medicinal products. The disclosure information includes the ID number of the Japan Registry of Clinical Trials (jRCT), the name of the entity sponsored by the company, the name of the medical research institution, the name of the governing body of the clinical research, and the total amount of the funds provided to the medical research institution. The information must be disclosed on the Internet in each fiscal year.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

As described in question 7.1, under the Clinical Research Act, the manufacturers of medicinal products are subject to a certain disclosure requirement. The information required to be disclosed regarding transfers of value includes certain research funding, donations, and compensation for writing manuscripts, making presentations or other entrusted work that are provided by the manufacture of medicinal products to the healthcare professional that is responsible for the clinical research or to a medical institution, university or other healthcare organisation to which the healthcare professional belongs. The information must be disclosed on the Internet in each fiscal year.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The JPMA has established the following self-regulatory codes for member companies, and these codes have been amended by the JPMA to ensure consistency of the disclosure requirements under the Clinical Research Act:

(a) *Transparency of Financial Relationships with Healthcare Professionals and Healthcare Organisations*

The JPMA has established a self-regulatory code for member companies to make publicly available information on financial relationships with healthcare professionals and healthcare organisations. These guidelines recommend that member companies make publicly available information on their financial relationships with healthcare professionals and healthcare organisations for the previous fiscal year through their websites. The information to be disclosed includes research and development expenses for clinical trials, academic research support expenses, lecture fees, manuscript/writing fees, consulting fees, expenses for provision of information, and entertainment expenses.

(b) *Transparency of Financial Relationships with Patient Organisations*

The JPMA has also established a self-regulatory code for member companies to make publicly available information on donations, grants, benefits in kind or any other support provided by them to patient organisations. These guidelines recommend that member companies make publicly available information on their financial contributions to patient organisations for the previous fiscal year through their websites. The information to be disclosed includes grants for supporting patient organisations, contributions to patient organisations' meeting costs, payments for writing articles, and consulting fees.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Prior to the implementation of the Clinical Research Act, if an individual healthcare professional refused to agree to the disclosure of transfers of value from a company, the company would not be able to force the healthcare professional to disclose the information. However, under the Clinical Research Act, the manufacturers of medicinal products are obliged to disclose certain information about transfers of values as described in question 7.2 above. In practice, pharmaceutical companies provide transfers of value to individual healthcare professionals only after obtaining their written consent to such disclosure.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Advertising of medicinal products on the Internet is subject to the same rules as pharmaceutical advertising regulations in any other media. Therefore, the Pharmaceutical Affairs Act and the Standards for Fair Advertising Practices also apply to such advertising.

Under the Pharmaceutical Affairs Act, the Minister of the MHLW or the prefectural governor may order the person who advertised the unauthorised medicinal products to stop such advertising. In addition, when the advertising of the unauthorised medicinal products is sent via the Internet, the Minister of the MHLW or the prefectural governor may request Internet providers to take measures to block such transmission of advertising on the Internet. For supervision and enforcement of these rules at the prefectural-level, the MHLW provides guidelines for monitoring and guidance concerning Internet advertising that violates the Pharmaceutical Affairs Act (Notice No. 1217-1 of December 17, 2014, issued by the Compliance and Narcotics Division of the Pharmaceutical and Food Safety Bureau of the MHLW).

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

As described in question 6.2, advertising prescription-only medicine to the general public is prohibited under the Standards for Fair Advertising Practices. Therefore, a pharmaceutical company is required to restrict access to the website that includes product information of prescription medicine.

The JPMA provides guidelines regarding such access restriction by the general public in the commentary on the Code of Practice, and it states that it is not necessary to block access to sites by using a password, if the sites meet the following requirements:

(a) the identity of the pharmaceutical company and of the intended audience (i.e., healthcare professionals only) should be readily apparent, and the site should be accessible only when the user confirms her status as a healthcare professional before entering the site;

(b) the content should be appropriate for healthcare professionals; and

(c) the content of the linked website should be appropriate for healthcare professionals and the owner (or author) of the linked website can be readily identified, when linking to any external websites.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

There are no specific rules regarding external linking from or to a pharmaceutical company-sponsored website. Whether the company will be responsible for the content of the independent website would need to be considered on a case-by-case basis. However, in general, if the integration of the content of independent websites and a company's website by such linking has a promotional effect on a specific medicinal product of the company, the content of independent websites could be considered part of pharmaceutical advertising that is subject to the Pharmaceutical Affairs Act. In that case, the company may be held responsible for the contents of the independent websites.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Information displayed on the website of the pharmaceutical company that may be accessible by the general public, must comply with the laws and rules on pharmaceutical advertising as described in question 1.1. A pharmaceutical company may place advertising for non-prescription medicine on its website; however, advertising prescription-only medicine to the general public on the website is prohibited as described in questions 6.2 and 8.1.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The rules on pharmaceutical advertising on the Internet as described in question 8.1 also apply to the use of social media by companies; however, there are no specific rules, laws or guidance focusing on the use of social media for pharmaceutical advertising.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The Guidelines on Information Provision were issued by the MHLW on September 25, 2018 to provide more rigorous and clear advertising rules for information provision in the course of the promotional activities of prescription-only medicines by pharmaceutical companies, such as sharing the results of research or providing scientific papers on unauthorised medicines to healthcare professionals upon their request.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Amendments to the pharmaceutical advertising regulations under the Pharmaceutical Affairs Act are expected to be discussed by the Diet in 2019. The introduction of a surcharge on a certain amount of sales of products as a sanction for violations of the advertising regulations on pharmaceutical products under the Pharmaceutical Affairs Act to strengthen the enforcement of those regulations is under discussion. The introduction of an administrative order by the MHLW to order violating parties to correct the contents of advertising that violates the advertising regulations under the Pharmaceutical Affairs Act is also expected to be discussed.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

For the past few years, Japan's pharmaceutical industry has been facing scandals regarding clinical research, such as possible data manipulation, conflicts of interest, and appropriateness of the use of clinical study results. As described in question 7.1, the Clinical Research Act came into force on from April 1, 2018. The further enforcement of the Clinical Research Act by the MHLW and implementation of the actions taken by pharmaceutical companies to comply with the Clinical Research Act should be closely monitored.

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# Korea

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The Act on Fair Indications and Advertisement (the "AFIA") regulates advertising in general, while the Pharmaceutical Affairs Act (the "PAA") specifically regulates the advertising of medicinal products.

The Korean Research-based Pharmaceutical Industry Association (the "KRPIA"), which counts numerous Korean subsidiaries of pharmaceutical multinationals as members, has established the Voluntary Code on Labelling and Advertising for Drugs (the "KRPIA Advertising Code"), which has been approved by the Korean Fair Trade Commission (the "KFTC").

### 1.2 How is "advertising" defined?

There are no specific provisions defining "advertising" under the PAA or the KRPIA Advertising Code. However, under the AFIA, an "advertisement" is defined as the act of broadly informing consumers of a particular business or its products by means of periodicals, newspapers, broadcasting, telecommunications, pamphlets, samples, tickets, the Internet, posters, signs, balloons, videos, records, books, movies, plays, the products of other businesses, and other similar media.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no rules expressly requiring that specific arrangements be put in place to ensure compliance with laws and codes of practice on advertising.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no legal or code requirements for companies to have specific SOPs governing advertising activities or to employ personnel with a specific role.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Under the PAA, medicinal products are divided into over-the-counter and prescription products, and all over-the-counter products and some prescription products, such as preventive drugs for a certain scope of infectious diseases, as set forth in the PAA and the Infectious Disease Control and Prevention Act, are permitted to be advertised publicly. For advertising to the general public by means of periodicals, newspapers, broadcasting (television and radio), the Internet, and other methods designated and publicly announced by the Ministry of Food and Drug Safety (the "MFDS"), an advance review and approval of the relevant promotional materials by the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (the "KPBMA") – another voluntary industry group which counts numerous Korean pharmaceutical companies as members – is required in principle.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

For breaches of the AFIA, the KFTC may order the advertisement to be discontinued or revised. For breaches of the PAA, the MFDS may order the advertisement to be discontinued. The recipients of such orders may seek to overturn such orders by filing appeals with the relevant administrative authority or with the courts.

### 1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

For breaches of the AFIA, the KFTC may impose fines of up to 2% of the sales of the relevant products during the period of the relevant breach. For breaches of the PAA, the MFDS may order the cancellation of the relevant product registrations or suspension of business according to the frequency and severity of the breach, or

impose fines *in lieu* of the suspension of business. In addition to these administrative sanctions, fines and/or imprisonment may be imposed through criminal proceedings. The foregoing are enforced to a reasonably strict degree in Korea.

While there have been no material court cases specifically against pharmaceutical companies in relation to the advertising of medicinal products, there are, from time to time, administrative sanctions imposed against pharmaceutical companies in this regard, to varying degrees.

If illegal advertisements of medicinal products cause damage to competitors, then competitors may seek damages through civil litigation. In addition, such competitors may report the illegal advertisements to the KFTC, the MFDS and the criminal prosecutor's office to request that administrative and criminal sanctions be imposed.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

Generally, any self-regulatory process and the supervisory and enforcement function of the competent authorities are conducted independently of each other. Therefore, in the case of advertising, even if a matter has already been assessed by a self-regulatory body (e.g. the KRPIA), the competent authorities (e.g. the KFTC or MFDS) may investigate and impose administrative sanctions according to the relevant laws (e.g. the AFIA or PAA), regardless of the results of any assessment by such self-regulatory body. That said, however, the head of the KRPIA may order a member company which is in contravention of the KRPIA Advertising Code, to rectify the same, and if the member company fails to comply, then the head of the KRPIA may request the relevant authorities to impose sanctions in accordance with the AFIA or PAA.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Regarding unfair competition, the KFTC may enjoin corrective measures based on the Monopoly Regulation and Fair Trade Act (the "MRFTA"), including, without limitation, orders to discontinue or revise the offending advertisements, or the imposition of fines.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Under the PAA, the advertisement of unauthorised medicinal products is prohibited. In addition, under the PAA, the advertisement of unauthorised indications or other items (such as usage or dosage) is prohibited in principle; provided, however, that as an exception, promotional materials of unauthorised indications or other items (such as usage or dosage) based on and citing clinical trial results which are medically or pharmaceutically recognised (i.e. which are published in reputable international or Korean journals) may be distributed to healthcare professionals.

However, under the KRPIA Advertising Code, materials regarding unauthorised medicinal products or indications shall not be used for advertising, but may be used for scientific discussion (only), even if such materials are based on clinical trial results which are published in reputable international or Korean journals. However, as there is no clear boundary between the foregoing, each case must be determined separately, based on its facts. For example, providing information regarding unauthorised medicinal products or indications during events organised by pharmaceutical companies alone is more likely to be viewed as advertising than during events organised by medical associations with the sponsorship of pharmaceutical companies.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

If information on unauthorised medicines and/or off-label information is published by pharmaceutical companies, the restrictions as stated in question 2.1 will apply.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

There are no rules specifically stating whether press releases fall within the scope of advertising. In this regard, the MFDS has opined that "whether a press release and its corresponding news article falls within the scope of advertising, and whether a press release and its corresponding news article breaches the PAA advertising regulations, will be determined on a case-by-case basis considering comprehensively detailed facts such as who is the advertiser, whether there has been a request for such advertisement, the background details leading up to the publishing of the news article, the relationship between the company and the newspaper company, and the contents of the newspaper", and "if any company related to a product, such as the manufacturer/importer/seller, provides economic benefits so that a news article is published, then such act can be considered an act of advertising".

Therefore, if any economic benefits are provided to journalists or newspaper publishers, and news articles regarding such unauthorised medicinal products and/or off-label information appear in the relevant newspaper, then such news articles will be deemed as the advertising of unauthorised medicinal products and/or off-label information.

In addition, even though no economic benefits are provided to journalists or newspaper publishers, if news articles regarding such unauthorised medicinal products and/or off-label information ultimately appear in the relevant newspaper, then there is still a possibility that such news articles will be deemed as the advertising of unauthorised medicinal products and/or off-label information, considering such factors as "who is the advertiser, whether there has been a request for such advertisement, the background details leading up to the publishing of the news article, the relationship between the company and the newspaper company, and the contents of the newspaper".

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Under the PAA, the advertisement of unauthorised medicinal products or indications is prohibited in principle. However, it is probably permissible for pharmaceutical companies to provide information regarding unauthorised medicinal products or indications to health professionals upon their request.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The *Ludwigs* case has not been reflected in the legislation or practical guidance in Korea. However, as mentioned in question 2.4, it is probably permissible for pharmaceutical companies to provide information regarding unauthorised medicinal products or indications to pharmacists upon their request.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Under the PAA, the advertisement of unapproved medicinal products or indications is prohibited in principle. However, it is probably permissible for pharmaceutical companies to provide information regarding unauthorised medicinal products or indications to institutions upon their request.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Involving health professionals in market research exercises regarding unauthorised medicinal products is probably permissible. However, such market research by healthcare professionals must not be a circuitous way of advertising unauthorised medicinal products. In addition, all the requirements for market research as stated in question 5.6 should be followed.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

There is no legislation specifically governing what information must appear in advertisements directed at healthcare professionals. However, under the KRPIA Advertising Code (which only applies to KRPIA members), advertisements to health professionals – in particular, journal advertisements – should contain: the product's brand name and active ingredient; the names and addresses of the manufacturer, importer and seller; and (in most cases) the relevant product information.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Under the PAA, the advertisement of unauthorised medicinal products is prohibited. In addition, under the PAA, the advertisement of unauthorised indications or other items (such as usage or dosage) is prohibited in principle; provided, however, that as an exception, where such unauthorised indications or other items (such as usage or dosage) are based on and cite clinical trial results which are medically or pharmaceutically recognised, such unauthorised items may be advertised to healthcare professionals. However, under the KRPIA Advertising Code, even if such unauthorised items are based on clinical trial results which are medically or pharmaceutically recognised, such items may be used only for scientific discussion, not advertising.

In addition, even if a study is not stated in the product information, if such study is not in conflict with authorised medicinal products or other items, and is based on (and cites) clinical trial results which are medically or pharmaceutically recognised (i.e. which are published in reputable international or Korean journals), such study may be advertised to healthcare professionals.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Under the PAA, an advertisement may not state that a drug has been designated, publicly acknowledged, recommended, or used by a doctor, dentist, oriental doctor, or pharmacist.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There are no laws or regulations specifically requiring a particular number of "head to head" clinical trials before comparative claims may be made. However, since the KRPIA Advertising Code states that comparative statements must be factual and fair, the results of "head to head" clinical trials should probably be used if the results of such "head to head" clinical trials and the results of meta-analysis differ from each other.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Under the KRPIA Advertising Code (which applies only to KRPIA members), the medicines subject to comparison must be described by the generic name of their active ingredient only, while under the AFIA and PAA there are no such provisions.

The AFIA and the KRPIA Advertising Code contain no provisions stipulating whether it is possible to refer to competitors' unauthorised products. However, if a comparative advertisement is based on and cites clinical trial results which are medically or pharmaceutically recognised, it is probably permissible to make comparisons with a competitor's unauthorised products in light of the PAA.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no rules specifically regulating the distribution of scientific papers and/or proceedings of congresses to healthcare professionals, unless economic benefits are also provided.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There are no rules specifically prohibiting "teaser" advertisements of medicinal products. However, if a "teaser" advertisement of a medicinal product creates misconceptions regarding the product by omission, then the advertisement may be in breach of the PAA and the KRPIA Advertising Code.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Under the PAA, the advertisement of unauthorised indications or other items (such as usage or dosage) is prohibited in principle; provided, however, that as an exception, where such unauthorised indications or other items (such as usage or dosage) are based on and cite clinical trial results which are medically or pharmaceutically recognised, then such unauthorised items may be advertised to healthcare professionals. In this regard, clinical trial results which are published in reputable international or Korean journals fall within the scope of "clinical trial results which are medically or pharmaceutically recognised" according to the relevant MFDS interpretation.

Therefore, in the example above, the holder of the MA for Product A may in any case promote the combination use so long as such combination use is stated as an authorised usage in Product A's SmPC. Regarding the question of whether the holder of the MA for Product B may also promote such combination use based on the approved SmPC for Product A, or whether the holder of the MA for Product B must first change the SmPC for Product B, considering the fact that such combination use of Product A and B has already been approved for Product A, there presumably will also be pre-existing clinical trial results which have already been published in reputable international or Korean journals. Under such presumption, it is likely that the holder of the MA for Product B may also promote such combination use (without changing the MA for Product B or Product B's SmPC); provided, however, that the holder of the MA for Product B shall cite relevant clinical trial results which are published in reputable international or Korean journals in relevant advertisements to healthcare professionals regarding such combination use.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

The PAA prohibits a pharmaceutical company from providing any economic benefits to physicians, employees, or founders of medical institutions for the purpose of promoting drugs, except for certain activities expressly permitted under the Enforcement Decree to the PAA (which is the Ordinance of the Ministry of Health and Welfare (the "MOHW"): the "Enforcement Decree").

In addition, the MRFTA prohibits companies from unfairly attracting or soliciting the customers of their competitors. Based on this, both the KRPIA and the KPBMA have established voluntary ethical codes on fair competition, both of which prohibit pharmaceutical companies from providing any economic benefits to healthcare professionals, except for certain expressly permitted activities. In addition, such voluntary ethical codes have each been formally approved by the KFTC (the "KRPIA Fair Competition Code" and the "KPBMA Code", respectively).

Under the Enforcement Decree, the KRPIA Fair Competition Code, and the KPBMA Code, it is permissible to provide health professionals with a minimum amount of samples (with the word "sample" inscribed on the same) for them to become familiarised with a product's characteristics, such as shape, colour, taste and smell.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

In principle, it is not possible to give gifts or donations of money to healthcare professionals, as such activity probably constitutes a breach of: the MRFTA, which prohibits companies from unfairly attracting or soliciting the customers of competitors; the PAA, which prohibits the presentation of economic benefits to physicians, employees, or founders of medical institutions for the purpose of promoting drugs; the Criminal Code, which prohibits both the bribery of public officials (e.g. healthcare professionals working at public healthcare institutions) and the unlawful solicitation of others to act in contravention of their fiduciary duties (e.g. healthcare professionals working at private healthcare institutions); and the Improper Solicitation and Graft Act, which prohibits the bribery of public officials (e.g. healthcare professionals working at public healthcare institutions).

However, under the Enforcement Decree and the two voluntary industry codes (i.e. the KRPIA Fair Competition Code and the KPBMA Code), it is permissible for a pharmaceutical company to provide certain economic benefits to participants during its product presentations (i.e. in the case of product presentations conducted by visiting individual medical institutions: (i) food and beverages of up to KRW 100,000 per day (up to four times per month); and (ii) promotional materials of up to KRW 10,000 which includes the name of a pharmaceutical company or the name of its product; and in the case of product presentations held domestically by inviting HCPs from multiple medical institutions: (i) the actual cost of domestic travel; (ii) souvenirs of up to KRW 50,000; (iii) lodging; and (iv) food and beverages of up to KRW 100,000); provided, however, that nurses must not be provided with any of the aforementioned economic benefits, even though they participate in product presentations.

Finally, any gifts or donations that are, at face value, in compliance with the foregoing KFTC-approved industry codes – and hence outwardly in compliance with applicable laws such as the MRFTA – will nevertheless be deemed in breach thereof if they are contingent on continued or increased prescriptions of medicinal products. Note that this is an overriding principle applicable to all gifts or donations discussed in this chapter.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

In principle, it is not possible to give gifts or donations of money, to donate equipment, or to fund the cost of medical or technical services to institutions such as hospitals, as such activity probably constitutes a breach of: the MRFTA, which prohibits a company from unfairly attracting or soliciting the customers of competitors; and the PAA, which prohibits a pharmaceutical company from providing any economic benefits to physicians, employees, or founders of medical institutions for the purpose of promoting drugs, except for certain activities expressly permitted under the Enforcement Decree.

However, under the KRPIA Fair Competition Code and the KPBMA Code, it is permissible to donate medicinal products to medical institutions for charitable purposes, subject to the submission of a prior report to the KRPIA or the KPBMA, respectively, provided, as always, that they are not contingent on continued or increased prescriptions of medicinal products (see question 4.2). No monetary limits apply.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

It is not possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns. Such provision would be in breach of: the MRFTA, which prohibits a company from unfairly attracting or soliciting the customers of competitors; the PAA, which prohibits the pharmaceutical company from providing any economic benefits to physicians, employees, or founders of medical institutions for the purpose of promoting drugs, except for certain activities expressly permitted under the Enforcement Decree; the Criminal Code, which prohibits both the bribery of public officials (e.g. healthcare professionals working at public healthcare institutions) and the unlawful solicitation of others to act in contravention of their fiduciary duties (e.g. healthcare professionals working at private healthcare institutions); and the Improper Solicitation and Graft Act, which prohibits the bribery of public officials (e.g. healthcare professionals working at public healthcare institutions).

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

It may constitute a breach of the PAA and the MRFTA to offer unfair or excessive volume-related discounts, as compared to normal trade practices. That said, however, it is generally accepted that discounts which are not unfair or excessive compared to normal trade practices and are given based on certain standards which are applied equally to all institutions, are in fact permissible.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

It is absolutely not possible to offer to provide (for free), or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products, as this would be in breach of the PAA and the MRFTA. As alluded to in question 4.2, all gifts or donations will be deemed in breach of the PAA and the MRFTA if they are contingent on continued or increased prescriptions of medicinal products. In addition, the provision of training on its use linked to the purchase of a particular medicine may be acceptable, whereas the provision (for free) of apparatus for administration linked to the purchase of a particular medicine may not be acceptable, since it may be deemed as additional economic benefits (unlike the provision of training on its use).

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Refund schemes for defective products are permissible, provided that the refunding company receives the defective product in exchange for the refund. Otherwise, the refund without return of the defective product may be in breach of the PAA, which prohibits the pharmaceutical company from providing any economic benefits to physicians, employees, or founders of medical institutions for the purpose of promoting drugs, except for certain activities expressly permitted under the Enforcement Decree. This applies to both prescription-only and over-the-counter medicines.

In addition, where any medicinal product in the market encounters problems regarding its efficacy or safety, due to non-compliance with the provisions of the PAA, such product must be recalled from the market.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Under the KRPIA Fair Competition Code and the KPBMA Code, pharmaceutical companies may not donate to, or otherwise sponsor, healthcare physicians or medical institutions directly, but rather

may donate only to medical academic or research organisations for certain projects relating to Continuing Medical Education ("CME"), or else sponsor CME academic congresses independently held by such organisations. In addition, a donation or sponsorship may only be provided where the KRPIA or the KPBMA deems such donation or sponsorship to be proper, and only through the procedures stipulated by the KRPIA or KPBMA.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

There are certain anti-bribery rules which may apply to interactions between pharmaceutical companies and healthcare professionals or healthcare organisations, as follows: (i) the PAA, which prohibits the presentation of economic benefits to physicians, employees, or founders of medical institutions for the purpose of promoting drugs; (ii) the Criminal Code, which prohibits both the bribery of public officials (e.g. healthcare professionals working at public healthcare institutions) and the unlawful solicitation of others to act in contravention of their fiduciary duties (e.g. healthcare professionals working at private healthcare institutions); and (iii) the Improper Solicitation and Graft Act, which prohibits the bribery of public officials (e.g. healthcare professionals working at public healthcare institutions). The competent authority regarding pharmaceutical advertising is the MFDS, while the competent authorities regarding items (i) to (iii) above are, respectively: (i) the MOHW; (ii) the prosecutor's office; and (iii) the Anti-Corruption and Civil Rights Commission (the "ACRC"). The MOHW and the ACRC will not investigate breaches of the PAA advertising rules; however, the prosecutor's office may investigate the breach of the PAA advertising rules from the perspective of criminal sanctions (and from the perspective of administrative sanctions, the MFDS will investigate the same).

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

It is in breach of the PAA and the MRFTA for pharmaceutical companies to offer hospitality to Korean healthcare professionals contingent on continued or increased prescriptions of medicinal products, or to otherwise promote medicinal products, even if this takes place in another country. Provided, however, that it is permissible for a pharmaceutical company to provide certain economic benefits for healthcare professionals participating at its product presentations (held in Korea) to the extent expressly permitted under the Enforcement Decree, the KRPIA Fair Competition Code, and the KPBMA Code (see question 4.2).

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Under the PAA, the KRPIA Fair Competition Code, and the KPBMA Code, only the following are permitted for those participating as speakers, presenters, moderators, and panellists at meetings not directly sponsored or organised by a company itself, who are selected by the society or institution holding or managing the relevant meetings: sponsorship of transportation fees; registration fees for conferences; the costs of meals; and the costs of lodging, all within the scope expressly permitted by the Enforcement Decree, the KRPIA Fair Competition Code, and the KPBMA Code. In addition, all sponsorship payments must be made to the KRPIA or the KPBMA, which will provide the sum paid by pharmaceutical companies to the society or institution holding or managing the relevant meeting (and not directly to the participants), and as always, must not be contingent on continued or increased prescriptions of medicinal products (see question 4.2).

For meetings directly sponsored or organised by a company, see question 5.3.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Under the Enforcement Decree, the KRPIA Fair Competition Code, and the KPBMA Code, it is expressly permissible to provide the actual cost of domestic travel, lodging, food and beverages and souvenirs for healthcare professionals participating in product presentations organised by pharmaceutical companies which are related to their products. However, such events should not be held in foreign countries. In addition, those product presentations where lodging is provided to physicians should be approved in advance by the KRPIA or KPBMA, and all other product presentations should be reported in advance to the KRPIA or the KPBMA.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Payment to doctors for their expert services such as lecturing and consulting is not expressly described as a permitted economic benefit under the Enforcement Decree. However, considering the official interpretation of the MOHW, such payment may be possible, on condition that it can be shown that such payment is compensation at fair market value for a *bona fide* service, and has not been used as a means for providing unfair economic benefits to doctors.

In addition, both the KRPIA Fair Competition Code and the KPBMA Code expressly allow a pharmaceutical company to pay lecture fees and/or consulting fees based on certain requirements, as follows:

In the case of lectures: (i) lecture fees shall be an amount of up to KRW 500,000 per each lecture lasting up to one hour, up to a limit of KRW one million per day – and the total amount of lecture fees per year shall not exceed KRW three million per HCP (including all taxes); provided, however, that up to KRW five million per year may be recognised as the annual ceiling amount when there is a justifiable need, such as when new products or new indications are the lecture topics or where there is a limited number of HCPs equipped with the expertise required for lectures; and (ii) lectures must be attended by 10 or more audience members (excluding the lecturer).

In the case of consulting fees: (i) consulting fees shall be an amount of up to KRW 500,000 per each consulting session, up to a limit of KRW one million per day – and the total amount of consulting fees per year shall not exceed KRW three million per HCP (including all taxes); provided, however, that for consultations related to the pharmacoeconomic analysis of pharmaceutical products, or consultations related to R&D/clinical studies, or the like, if the services provided in excess of the above-mentioned fee limit can be objectively recognised, then such fee limit shall not apply; and (ii) consulting fees shall take into consideration such factors as the level and degree of the consultation, and the expertise, knowledge, and experience of the consultation, but shall be calculated based on the actual time and effort exerted in providing the consultation.

### 5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

It is possible to pay a reasonable amount to those doctors taking part in post-marketing surveillance. The PAA and the MFDS's "New Drug Re-examination Guidelines" apply to such studies. Note, however, that paying doctors taking part in post-marketing surveillance activities which are not specifically required under the PAA and the New Drug Re-examination Guidelines – absent evidence of the necessity and propriety of such surveillance – might be deemed by the MOHW and the KFTC to be in breach of the PAA and the MRFTA.

### 5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Under the KRPIA Fair Competition Code and the KPBMA Code, pharmaceutical companies may provide (i) food and beverages or gifts of up to KRW 100,000 per healthcare professional, or (ii) moderate compensation of up to KRW 100,000 per healthcare professional for market research which requires a response time of 30 minutes or more, provided that (a) pharmaceutical companies may perform the market research only through third-party market research institutions, and (b) such market research institutions should not disclose the identity of the participants to the pharmaceutical company performing the relevant market research, and *vice versa*.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

It is possible to advertise non-prescription medicines to the general public.

The PAA sets forth the restrictions which apply to advertising of non-prescription medicines. Specifically, the Ordinance of the Prime Minister (the "Ordinance") and Annex 7 of the Ordinance stipulate in detail several conditions, including prohibitions against advertising which creates consumer misconceptions, advertising using prizes or gifts, and advertising using patient testimonials, as well as the requirement to pre-approve advertisements. Furthermore, the AFIA prohibits exaggerated, deceitful, unfairly comparative, and defamatory indications and advertisements.

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

In principle, it is not possible to advertise prescription-only medicines to the general public. However, on an exceptional basis, some preventive drugs for a certain scope of infectious diseases, as set forth in the PAA and the Infectious Disease Control and Prevention Act, are permitted to be advertised publicly.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Although it is not possible to advertise prescription-only medicines to the general public, genuine disease awareness campaigns which encourage those with a particular medical condition to consult their doctor, without mentioning or implying any specific medicines, are permitted.

Under Annex 7 of the Ordinance, no advertisement shall be allowed which expressly or impliedly refers to medicines for which public advertisement is prohibited, by indicating a specific disease.

### 6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

There are no rules specifically stating whether press releases fall within the scope of advertising. In this regard, the MFDS has opined that "whether a press release and its corresponding news article falls within the scope of advertising, and whether a press release and its corresponding news article breaches the PAA advertising regulations, will be determined on a case-by-case basis considering comprehensively detailed facts such as who is the advertiser, whether there has been a request for such advertisement the background details leading up to the publishing of the news article the relationship between the company and the newspaper company, and the contents of the newspaper", and "if any company related to a product, such as the manufacturer/importer/seller, provides economic benefits so that a news article is published, then such act can be considered an act of advertising".

Therefore, if any economic benefits are provided to non-scientific journalists or newspaper publishers, and news articles regarding prescription-only medicines appear in the relevant newspaper, then such news articles will be deemed as direct-to-consumer ("DTC").

In addition, even though no economic benefits are provided to non-scientific journalists or newspaper publishers, if news articles regarding such prescription-only medicines ultimately appear in the

relevant newspaper, then there is still a possibility that such news articles will be deemed as DTC, considering such factors as "who is the advertiser, whether there has been a request for such advertisement, the background details leading up to the publishing of the news article, the relationship between the company and the newspaper company, and the contents of the newspaper". For press releases to refer to developments in relation to as yet unauthorised medicines or unauthorised indications, please see question 2.3.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

There are no rules specifically regulating the description of products and research initiatives as background information in corporate brochures/annual Reports. However, if such descriptions can be interpreted as advertising for medicines, considering their form and content as a whole, the restrictions that apply to the advertising of medicines under the PAA may also apply to such descriptions.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There are no rules specifically regulating meetings with and the funding of patient support groups.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Under the PAA, no advertisement shall be allowed which offers free gifts. Therefore, in principle, it is not possible for a pharmaceutical company to provide economic items or benefits for patients.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Under the PAA and its subordinate regulations, companies are obligated to disclose details of clinical trials to the MFDS and/or the relevant Institutional Review Board ("IRB"). Prior to the clinical trials, relevant documents such as the protocol and patient consent forms shall be submitted and approved by the MFDS and/or the relevant IRB (in the case of clinical trials regarding approved indications of approved products, MFDS approval is not required). During the clinical trials, serious and unexpected adverse effects shall be reported to the MFDS and the relevant IRB.

In addition, under the PAA and its subordinate regulations, companies are obligated to prepare reports on providing economic benefits to medical institutions/HCPs (including payments for clinical trials) within three months after the end of each fiscal year, and to maintain such reports and relevant supporting documentation for five years. In addition, the MOHW may request companies to submit such reports and supporting documentation when it deems it to be necessary, and companies may not refuse such request without justifiable reasons.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no such requirement.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

There is no such requirement.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Under the PAA and its subordinate regulations, companies are obligated to prepare reports on providing economic benefits to medical institutions/HCPs (including payments for clinical trials) within three months after the end of each fiscal year, and maintain such reports and relevant supporting documentation for five years. In addition, the MOHW may request companies to submit such reports and supporting documentation when it deems it to be necessary, and companies may not refuse such request without justifiable reasons (see question 7.1).

Under the PAA, an individual healthcare professional who has received economic benefits from a company may not restrict such company from submitting such reports and supporting documentation to the MOHW.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Under the PAA and MFDS's relevant opinion, the advertisement of prescription-only medicines to the general public by means of the Internet is prohibited, unless such prescription-only medicines are preventive medicines for a certain scope of infectious diseases, as set forth in the PAA and the Infectious Disease Control and Prevention Act, or a pharmaceutical company places approved information regarding its prescription-only medicines on its main company website (as opposed to information placed on multiple discrete websites). In addition, the advertisement of medicines to the public by means of the Internet shall be pre-approved by the KPBMA. Also, the MFDS has the authority to impose sanctions against any advertisements of medicines which breach the PAA, including ordering the discontinuation of such advertisements.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

There are no specific legal requirements for website security to ensure that members of the general public do not have access to sites intended for health professionals. However, log-in/password control may be the safest way to reduce DTC legal risks.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

There are no rules specifically regulating the content of such independent websites. In addition, there are no specific interpretations of relevant authorities in this regard. With that said, however, note the following:

(i) In the case of linking to independent websites from a company's website, in principle the company will not be responsible for the contents of the independent sites. However, if such independent sites contain contents which are in breach of advertising regulations, and the company links its own website to such contents, then the possibility cannot be ruled out that the company will in fact be held responsible for the contents of such independent sites, since it may be interpreted that the company has used the contents of such independent sites (which are in breach of advertising regulations) for the advertisement/promotion of the company itself or its own products.

(ii) In the case of reverse linking from an independent website to a company's website, the company is unlikely to be responsible for the content of such independent site. In this regard, if the company itself is not involved in such reverse linking, then there are no grounds to blame the company. In addition, even if the company is involved in such reverse linking (e.g., when the company has posted on the independent site a banner advertisement linking to the company's own website after paying advertisement expenses to the operator of such independent site), the company is still not likely to be responsible for the contents of the independent site, since such linking to the company's website is merely to introduce the company's website to persons who have already visited and accessed the independent site themselves, without any inducement from the company.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

There are no legal restrictions on the information which a pharmaceutical company places on its main website that may be accessed by members of the public, provided that the AFIA and the PAA apply to any information which can be deemed as the advertising of medicines. Furthermore, as an exception to the prohibition against advertising prescription-only medicines to the general public, a pharmaceutical company may in fact place approved information regarding its prescription-only medicines on its main company website (as opposed to information placed on multiple discrete websites), despite the fact that it may be accessed by members of the public.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no specific rules, laws or guidance, controlling the use of social media by companies. However, specific rules, laws and guidance applicable to the Internet, such as pre-approval by the KPBMA, will also apply to social media.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

In connection with pharmaceutical advertising, there were no significant developments in the last year.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

In the field of pharmaceutical advertising, there are no specific significant developments expected in the next year.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

There are no specific general practice or enforcement trends that have become apparent in Korea over the last year or so, in relation to the advertisement of medicinal products.

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Since its establishment in 1993, HMP Law, one of Korea's leading full-service law firms, has been at the forefront in responding to the ever-changing needs of foreign clients doing business in Korea. Having developed strengths in such fields as corporate law, finance, banking and capital markets, litigation and arbitration, fair trade, tax and accounting, and of course, pharmaceuticals and healthcare, HMP Law has forged its international reputation by advising clients and liaising effectively with foreign law firms on complex legal matters. In addition to having Korean and foreign-licensed attorneys, HMP Law has on its staff Korean and U.S.-licensed certified public accountants, as well as patent and customs specialists. Combining an in-depth knowledge of domestic laws and regulations with a global understanding of the international business environment, HMP Law is dedicated to providing the highest level of professional service.

# Macedonia

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising, and in general marketing of medical products in the Republic of North Macedonia is regulated by the Law on Medicinal Products and Medical Devices (Official Gazette of the Republic of Macedonia no. 38/2004 – as amended from time to time) and the Guidelines on the manner of advertising of medicinal products and medicinal devices (Official Gazette of the Republic of Macedonia no. 66/2008). However, the advertising of medical products shall also be in the line with the Law on Consumer Protection (Official Gazette of the Republic of Macedonia no. 106/2007 – as amended from time to time), the Law on Healthcare Protection (Official Gazette of the Republic of Macedonia no. 43/12– as amended from time to time), and the Code of professional ethical responsibilities and rights of healthcare professionals (HCPs) with a university degree in pharmacy (Official Gazette of the Republic of Macedonia no. 33/2014).

### 1.2 How is "advertising" defined?

The Law on Consumer Protection, as the general law that provides the general principles of advertising all kind of products that are placed on the market in North Macedonia, defines the advertising of products and services as any form of making a presentation related to a trade or business activity, craft or profession to promote the supply of products or services, including real estate, rights and obligations.

The Law on Medicinal Products and Medical Devices particularly defines the advertising of medicinal products as follows: "*Advertising of medicinal products shall mean any form of disseminating information in a written, picture, sound, oral, electronic, digital or any other form, directed to the general or professional public for the purpose of promoting prescription of medicinal products, stimulating dispense of medicinal products, their supply, sale and use*."

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The Laws of North Macedonia do not prescribe an obligation for companies to have a special in-house unit/sector in charge of advertising. However, bearing in mind that advertising must be approved prior to publishing, all companies who are applicants for the purpose of advertising, must be in compliance with positive legislation governing the advertising of medicinal products and devices. Furthermore, if any advertisement is found to be in breach of legislation, such may be cancelled by the competent authorities, and sanctions may be applied to companies found to be in breach of positive legislation governing the advertisement of medicinal products and devices.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no specific mandatory requirements for companies to have SOPs governing advertising activities. The Guidelines on the manner of advertising of medicinal products and medicinal devices do, however, provide that advertising through the promotion of medicinal products and devices directed to the expert public shall be done by healthcare professionals who have medical, dental or pharmaceutical university degrees.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

In accordance with the Law on Medicinal Products and Medical Devices, marketing authorisation holders and manufacturers of medicinal products that are not subject to medical prescription, may inform the general public about the medicinal product characteristics in line with the summary of the product characteristics or patient manual, in an objective manner and upon prior approval from the Macedonian Agency for Medicines and Medical Devices. Advertising prescription-only medicine is prohibited. Advertising medical products and medical devices to the professional public is not subject to prior authorisation.

The Law and by-laws do not specifically prescribe the procedure for acquiring advertising approval.

The Macedonian Agency for Medicines and Medical Devices is the regulator that issues approvals for the advertisement of medicinal products and medicinal devices. The Macedonian Agency for Medicines and Medical Devices practice in approving advertising of medical products shows that the company shall require prior approval for each advertisement, and for each medium separately

(newspapers, TV commercials, online advertisements, etc.). To acquire approval to place an advertisement, the applicant shall submit a written request indicating all data referring to the medical product/device in question, the type of medium to be used and type of advert to be placed, as well as the proposed text of the advertisement itself. In addition to the request, the applicant shall provide the marketing authorisation for the product/device in question, and the SmPC, as well as the patient manual. The Agency has prescribed administrative fees for the purpose of acquiring approval for advertising depending on the type of advertisement and medium.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Pharmaceutical inspectors, during the supervision of medicinal products and devices, are entitled to prohibit any advertising of medicinal products which are inconsistent with the Law and to order the removal or destruction of the material used to advertise the medicinal product, as well as to ban any advertising of a medical device that is against the Law and to order the removal or destruction of a material used to advertise a medical device in a manner not corresponding to this Law.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Article 154 of the Law on Medicinal Products and Medical Devices prescribes a fine in the amount of EUR 50,000, and in MKD, a counter-value shall be imposed for committing a misdemeanour on a legal entity if it:

1) offers direct or indirect financial or material benefit to the persons who prescribe or administer the medicinal products;
2) advertises prescription medicinal products to the general public through the mass media;
3) advertises a medicinal product in a manner contrary to the Law, thus misleading the user;
4) publicly advertises medicinal products through addressing children;
5) publicly distributes free samples of medicinal products; and/or
6) publicly advertises medicinal products without a marketing authorisation.

A fine in the amount of 30% of the determined fine for the legal entity shall also be imposed on the responsible person in the legal entity for the misdemeanours referred to in this Article.

A fine in the amount of EUR 5,000 to MKD 7,500 in counter-value shall be given to the employee in their legal entity for having perpetrated this misdemeanour.

Furthermore, Article 155 of the Law prescribes a fine in the amount of EUR 30,000, and in MKD a counter-value shall be imposed for committing a misdemeanour on a legal entity if it:

1) advertises medicinal products or medical devices contrary to Article 92 of the Law (rules on advertising to medical professionals);
2) provides information about the goals stipulated in Article 93 paragraph 2 in a manner contrary to Article 93 paragraph 3 of the Law (enabling persons prescribing or dispensing medicinal products to acquire additional knowledge on new medicinal products in a manner exceeding the limit of the scientific and expert objectives of such education); and/or
3) fails to advertise the medicinal products according to Article 94 of the Law (informing the general public about the medicinal product characteristics which is not in line with the summary of product characteristics for the patient manual, or is not made in an objective manner and upon prior approval from the Macedonian Agency for Medicines and Medical Devices).

A fine in the amount of 30% of the determined fine for the legal entity shall also be given to the responsible person in the legal entity for the misdemeanours referred to in this Article.

A fine in the amount of EUR 3,000 to MKD 4,500 in counter value shall be imposed on the employee in the legal entity having perpetrated this misdemeanour.

With regard to the misdemeanours determined by this Law, the competent court shall conduct a misdemeanour procedure and impose misdemeanour sanctions. With regard to the misdemeanours laid down in Articles 154, 155, 155-a and 155-b of the Law, the pharmaceutical inspector shall be obliged to issue to the perpetrator of the misdemeanour a misdemeanour payment order, in accordance with the Law on Misdemeanours.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The competent authorities shall investigate matters constituting a breach of legislation, in accordance with their competences stipulated by law, regardless of whether such is already being assessed by a self-regulatory body. Authorities should take up matters based on adverse findings of self-regulatory bodies if such matters are in the scope of such authority competences.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The Law against disloyal competition (Official Gazette of the Republic of Macedonia no. 80/99) prescribes measures against unfair competition. In accordance with the Law, should one, when conducting business, and for the purposes of the competition, act contrary to good business practices or contrary to the principle of conscientiousness and honesty, such person/entity will be prohibited by the competent court from further performing those acts and actions and will be liable for the damage such acts and actions caused, under conditions determined by the Law. A proposition may be filed with a competent court and such court may reach a decision barring the entity in breach of the legislation from undertaking activities as recognised in the breach. Furthermore, the fair competition is protected by the Law on the Protection of Competition, implementation of which is supervised by the Commission for protection of competitions of North Macedonia.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Article 95 of the Law on Medicinal Products and Medical Devices prescribes that it is prohibited to publicly advertise medicinal products that have no marketing authorisation. Further, advertising medicinal products that have no marketing authorisation shall be considered a misdemeanour in accordance with the Law.

In addition, the Guidelines on the manner of advertising of medicinal products and medicinal devices, adopted by the Minister of health, based on the Law on Medicinal Products and Medical Devices, prescribe that advertising shall be done through providing information on the medicinal products to medical professionals and the public by the holder of the marketing authorisation.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

No, information may not be published for medicinal products that have no marketing authorisation, as described above in the answer to question 2.1.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

No, it is not possible; please see the answers to questions 2.1 and 2.2 above.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

No, it is not possible; please see the answers to questions 2.1 and 2.2 above.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Up to this point in time, the prohibition for providing any type of information regarding products lacking a marketing authorisation has not been lifted.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

There is no explicit provision in Macedonian legislation with regards to this. However, considering the definition of "advertising" as well as the prohibition of advertising unauthorised medicine, it should be expected that any such disbursement of information related to unauthorised medicine would be prohibited.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The Law on Medicinal Products and Medical Devices does not strictly regulate the possibility for healthcare professionals to be engaged in market research exercises concerning possible launch materials for medicinal products or indications yet unauthorised. The Law on Healthcare Protection does, however, provide for the possibility for healthcare professionals to be engaged as consultants and advisors, individually or in a group, for the purpose of providing services as speakers or meeting chairpersons, participation in medical/scientific studies, clinical trials or training services, participation in advisory meetings and participation in market research. No specific guideline has been adopted for market research focusing on medicinal products.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Advertising medicinal products intended for medical professionals shall be done by marketing authorisation holders through advertisements placed in specialised literature, specialised periodically issued magazines and other specialised publications, as well as by the direct provision of information to the healthcare professionals who prescribe or dispense medicinal products.

Advertising prescription medicinal products to medical professionals shall only be allowed in terms of providing information in line with the summary of the product characteristics or concerning marketing conditions.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

In accordance with the Law on Medicinal Products and Medical Devices, advertising prescription medicinal products to medical professionals shall only be allowed in terms of providing information in line with the summary of the product characteristics or concerning marketing conditions.

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, the advertisement intended for the professional public is intended for the purposes of getting acquainted with the characteristics of the medicine, i.e. a

medical device, for the expert public to acquire knowledge about their therapeutic action.

If the advertisement is done through promotion of the medicine, i.e. the medical device, the holder of the authorisation must indicate the data on the date of obtaining the marketing authorisation or the date of the last change of the authorisation, and it must be updated, relevant and faithfully transmitted data indicating the correct source and literature from where the information was taken. In addition to this data, the promotion of the medicine, i.e. the medical device, may also include the sales data price of the medicinal product or medical device.

Regarding advertisements intended for the general public, such shall not contain any information referring to studies.

In accordance with the Guidelines, when advertising through promotion there should not be any:

1) encouragement to prescribe, issue, procure, recommend the use of or purchase of the medicine or medical device through offering and giving rewards in the form of money, gifts or giving and enabling any other kind of property and inadequate benefit, that is, to promise or give some privilege or award;
2) encouragement to the professional public that one medicine, i.e. a medical device, can be replaced by another medicine or medical device from the same therapeutic group, without clear medical treatment indications;
3) made allegations or conclusions about the action of the medicine, i.e. medical device subject to clinical trials in the country or abroad;
4) promotion of a medicine or medical device that is in the process of changing the summary report on the properties of the medicinal product and of the product user manual;
5) a use of the summary of product characteristics and guidelines for patients/users, in a text of which the font size is less than 3 mm, that is, to use another method of printing that disables easy reading and understanding of the text;
6) publishing of information through the media, which is used in the procedure for advertising of healthcare institutions, i.e. specialised stores;
7) reducing the significance of the warning about the measures of caution or adverse medicine reactions, respectively the medical device, specified in the approved summary or the product characteristics report, as well as the instructions for use;
8) reducing the therapeutic value of another medicine i.e. medical device, that has a marketing authorisation or in any other way, arouse doubt in the value of another medicine or medical device;
9) use of the Ministry of Health, the Macedonian Agency for Medicines and Medical Devices, i.e. other persons participating in the examination procedure and placing the medicine or medical device on the market;
10) use of materials that are protected by any form of protection of intellectual property without prior consent of the owner of such rights;
11) use of postcards or other forms of written consignments of which the content may be available or readable to others other than the professional public; and
12) use of telephone, fax, e-mail or other electronic media of persons who belong to the ranks of the expert public without their clearly expressed prior consent, and who in such way are advertised or informed in their work.

When promoting a medicine or medical device by the holder of the authorisation, money or any other kind of benefit should not be offered to the expert public in order to encourage the prescribing, issuing, purchasing, or consumption of medicine or medical devices.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The Law on Medicinal Products and Medical Devices does not expressly prescribe any restrictions as to the inclusion of endorsements by healthcare professionals in promotional materials. It should, however, be noted that the Guidelines on the manner of advertising of medicinal products and medicinal devices stipulates that when advertising to the general public, recommendations made by a person who because of their popularity can affect the use of the medicine, i.e. the medical device, should not be used (the Guidelines do not specify which persons shall be considered popular in light of this).

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

The Law on Medicinal Products and Medical Devices generally prohibits comparing medicinal products and devices with other medicinal products and devices when advertising.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication, which had not yet been authorised in your jurisdiction?

In accordance with the provisions of the Law on Medicinal Products and Medical Devices, it shall be prohibited to publicly advertise a medicinal product by associating it with the characteristics it lacks, overstating its positive effects, exaggerating and describing the effects of the medicinal product in an inappropriate manner, **comparing it with other medicinal products** or misleading medicinal product users in any other way. In addition, the Law prescribes that it shall be prohibited to publicly advertise medicinal products that have no marketing authorisation.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

There are no special rules that govern the distribution of scientific papers as of this moment. In terms of pharmaceutical advertising, such advertising directed to healthcare professionals can be done in accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices through promotion and informing health professionals who prescribe medicinal products and devices, in professional magazines and other forms of promotion as well as sponsoring scientific and promotional gatherings for the expert public. Such advertising shall be done for the purpose of getting acquainted with the characteristics of the medicinal products or devices, and for the expert public to acquire knowledge about such products'/devices' therapeutic action.

### 3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

Laws governing the advertisement of medicines and medical devices do not *per se* regulate "teaser" advertisements, thus "teaser"

advertisements are not explicitly prohibited. However, it should be noted that all advertisements must contain the minimum information as stipulated within the Guidelines on the manner of advertising of medicinal products and medicinal devices and should be in compliance with the general rules for advertising as provided by the Law on Medicinal Products and Medical Devices.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

According to the Guidelines on the manner of advertising medicinal products and medicinal devices, the advertisement of medicine and medical devices shall be in accordance with the approved patient manual and summary of product characteristics.

Furthermore, Article 92 of the Law on Medicinal Products and Medical Devices prescribes that advertising medicinal products subject to medical prescription, intended for medical professionals shall only be allowed in terms of providing information in line with the summary of the product characteristics or concerning marketing conditions. Advertising contrary to the provision of Article 92 shall be considered a breach of legislation and can incur a penalty in the amount of EUR 30,000, and in MKD a counter-value shall be imposed for a misdemeanour on the legal entity in breach of this provision and a penalty in the amount of 30% of the determined fine for the legal entity shall also be imposed on the responsible person in the legal entity for the misdemeanour. The Law also prescribes a penalty in the amount of EUR 3,000 or MKD 4,500 in counter value, to be given to the employee in the legal entity having perpetrated the misdemeanour.

Bearing all of the above-mentioned in mind, the advertising of product characteristics not included in the SmPC would not be permitted.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Advertising medicinal products to medical professionals may be accompanied by the provision of one small pack of the authorised medicinal product, labelled as a "free sample" and "not for sale", except for medicinal products containing narcotic and psychotropic substances.

Furthermore, the Guidelines on the manner of advertising of medicinal products and medicinal devices provide that during the promotion of the medicinal product, i.e. a medical device, the promoters may give free samples of the said medical product, together with a copy of the approved Summary Report on the properties of the medicinal product and the patient's manual if:

1. the medicinal product or the medical device has a marketing authorisation to be placed on the market in the Republic of North Macedonia, i.e. they are registered in the register of medical devices in the Republic of North Macedonia;
2. the free sample of the medicine, i.e. the medical device, is solely intended for getting acquainted with the properties of the new medicine, i.e. the medical device;
3. the quantity of free samples is limited to 30-day defined doses of the medicine during one calendar year;
4. the free sample is in the smallest package of medicinal products, i.e. the smallest pack of a particular kind of medical device, as it is placed on the market, with a mark on the package stating "free sample, not for sale"; and
5. if the free sample of the medicinal product does not contain narcotic drugs or psychotropic substances.

As an exemption of the above, a free sample of the medicinal product, i.e. the medical device, can be given to persons of the professional public on their written request.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

In accordance with the Law on Medicinal Products and Medical Devices, upon advertising medicinal products, marketing authorisation holders or legal entities and natural persons acting on their behalf shall not offer gifts, direct or indirect financial or material benefit to persons who prescribe or dispense medicinal products, except such of small value and intended for performing healthcare activity.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

The Law on Healthcare Protection provides that one of the ways of financing public healthcare institutions can be done through gifts and donations.

In addition, the Law on Medicinal Products and Medical Devices provides that medicine can be donated with prior consent issued by the Minister of Health. Such donated medicine can be imported and used in accordance with its need, without the need for a marketing authorisation. Donated medicine must be labelled as donated as well as labelled free of charge, clearly and permanently. Authorisation for the import of donated medicine shall be issued by the Macedonian Agency for Medicines and Medical Devices.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, advertising medicinal products and devices intended for health professionals shall not be done in a manner, which encourages prescribing, issuing, procurement, recommending use or purchase of the medicine or medical device through offering and giving a reward in the form of money, giving gifts or giving and enabling any other kind of property and inadequate benefit, that is, promise of giving some privilege or award.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Prices of medicinal products are formed freely, except for the prescription-only medicinal products and the medicinal products that are on the list of essential medicinal products.

With regards to the formulation of prices, the Law on Medicinal Products and Medical Devices further prescribes that the pricing of medicinal products shall be performed in a manner, which is not discriminatory and does not allow dumping. The wholesale price of the medicinal products shall be calculated as the sum of the production price and wholesale margin.

If a manufacturer supplies healthcare institutions with medicinal products from its own production programme directly, or through their own wholesaler, the price of the medicinal product shall be identical with the production price of such product.

If a wholesaler supplies healthcare institutions with medicinal products, the price of such product cannot exceed the formed price for the product in wholesale, established by the methodology prescribed by the Government.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Unless offerings of insignificant value are provided (in accordance with the provisions regulating advertisements for healthcare professionals), offering such a package deal may be considered a breach of the Guidelines on the manner of advertising of medicinal products and medicinal devices, which provides that promoting products shall not be done in a manner that encourages the prescription or promotion of products as well as in breach of the ban for disloyal competition.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

There are no specific provisions regulating this, however, if advertisements contain information on how to collect an offered refund, it may be considered as misleading, especially bearing in mind the fact that advertisements may not contain information regarding the efficiency of the product.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Marketing authorisation holders may enable persons prescribing or dispensing medicinal products to acquire additional knowledge on new medicinal products and already marketed medicinal products, through organising and holding promotional seminars. Marketing authorisation holders are obliged to provide the information for the purposes referred to above, in a manner not exceeding the limit of the scientific and expert objectives of such education, being organised exclusively for acquiring new knowledge for the medicinal product and being directed solely at the persons prescribing or dispensing medicinal products.

Additionally, the Law on Healthcare Protection provides that healthcare workers and healthcare co-workers have the right and duty to train and improve in accordance with the needs of the healthcare institution in which they are employed. The healthcare professional may receive a donation and sponsorship from natural persons or entities, for participation in professional meetings, seminars, workshops, etc. for the purpose of further training and improvement. For the donation and sponsorship, previous approval shall be provided by the Ministry of Health. Donations and sponsorships shall be evidenced in the register of sponsors and donations *ex officio* by the Ministry of Health.

The Law on Donations and Sponsorships in public activities prescribes that a donation is a voluntary and impeccable aid of money, goods and/or services that does not directly benefit the lender and does not oblige the recipient to return the donation, which can be given for the purposes of public interest or to support the activities of the recipient.

The subject of donation and sponsorship in accordance with this Law can be:

- financial assets;
- any kind of goods and services, including material goods, own manufactured or procured; and
- legacies and other rights in traffic.

Donations and sponsorships must be in accordance with the activity of the recipient of the donation and sponsorship, and cannot be goods and services of which the traffic is prohibited by law.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

General anti-bribery rules are regulated by the Criminal code (Official Gazette of the Republic of Macedonia no. 37/9 – as amended). Such rules apply to any and all individuals and entities both in the private as well as the public sector. There are no special rules regulating the relationship between competent authorities for pharmaceutical advertising and anti-bribery/anti-corruption authorities. However, under the Law on Medicinal Products and Medical Devices, pharmaceutical inspectors are authorised to investigate and prosecute offerings and/or givings of gain in breach of the Law provisions, which may also be considered as a breach of anti-bribery/anti-corruption legislation. As administration officials, the inspectors shall be entitled to initiate criminal proceedings before competent authorities.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Offering hospitality to healthcare professionals is in general regulated by the Law on Medicinal Products and Medical Devices and the Guidelines on the manner of advertising of medicinal products and medicinal devices. Covering the essential costs for transport, accommodation and the attendance fee is considered a sponsorship to healthcare professionals in light of the Law and the Guidelines. There is no specific threshold prescribed therein and there are no specific rules regarding choosing the location of the event. It should, however, be taken into consideration that all costs should strictly be connected to the purpose of the scientific event in question.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, sponsoring, in the sense of the guidelines, consists of covering the necessary travel expenses, accommodation and payment of the mandatory costs for participation in the professional event (registration fee) for the duration of the expert event. The Guidelines prescribe that advertising a medicine or medical device can be performed by the applicant of the advertisement by sponsoring scientific and promotional gatherings, professional lectures, congresses, seminars, as well other expert events attended by the expert public that are educational and consistent with scientific achievements.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Sponsoring healthcare professionals to attend scientific meetings shall be considered covering of essential expenses for transport, accommodation and attendance fees, whereas covering expenses for concomitant events such as tourist travels, sport and other similar events, which are not considered expert meetings/events, shall not be considered sponsorship. Any additional offerings may be considered as direct or indirect financial or material gain and is thus prohibited. In accordance with the penalty provisions of the Law on Medicinal Products and Medical Devices, a fine in the amount of EUR 50,000 in MKD counter-value shall be imposed for a misdemeanour on a legal entity if it offers direct or indirect financial or material benefit to the persons who prescribe or administer medicinal products. With regard to all misdemeanour sanctions prescribed, the proceedings shall be conducted by a competent court and such court shall impose misdemeanour sanctions.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Healthcare workers and healthcare associates may be consultants and advisors, individually or within a group, for the purpose being to provide services as speakers or chairpersons on scientific meetings, and to participate in medical/scientific studies, clinical trials or training services, in advisory meetings and in market research, where such participation includes a fee and/or travel.

The relationship between the healthcare professionals and the contracting entities for the purpose described above shall be set out in advance, by a written agreement, stating in particular:

- a description of the services and the basis for payment thereof;
- the clear identification of the justified need for such services by consultants and/or advisers;
- clearly defined criteria on the basis of which the consultants or councillors were selected and their direct connection with the identified need and the persons responsible for the selection of consultants and/or advisers;
- an explanation for the necessity of engaging the number of consultants or advisors according to the goal to be achieved;
- a provision that the engagement of healthcare professionals is not intended to recommend, prescribe, buy, procure, sell or administer a particular remedy;
- the amount of the fee for the service that is appropriate to the market value of the provided service;
- an obligation for the contractor to record the services provided by the healthcare professionals; and
- the obligation of the healthcare professionals to inform when they are acting in public or when writing about an issue that is the subject of the contract or any other matter regarding the contractor and/or adviser of the service provider.

The offering and provision of consulting services to patients by healthcare professionals employed in a public healthcare institution, outside the healthcare institution in which they are employed, is prohibited.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes, please see the answer to question 5.4 above.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes, please see the answer to question 5.4 above.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Marketing authorisation holders and manufacturers of medicinal products that are not subject to a medical prescription may inform the general public about the medicinal product characteristics in line

with the summary of product characteristics or patient manual, in an objective manner and upon prior approval from the Macedonian Agency for Medicines and Medical Devices.

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, the advertising of medicine, i.e. a medical device intended for the general public, should be carried out through messages that contain clear information that the product being advertised is a medicine, that it is a medical device, and they should not provide a misconception to the patient.

When advertising, the message should contain at least:

1) the name of the medicinal product i.e. the medical device, i.e. International Non-proprietary Name (INN) for a medicinal product containing only one active substance;
2) the manner of use and the data necessary for the correct use of the medicine i.e. the medical device; or
3) a visible, legible and understandable written, drawn or spoken warning for the patient/user, that instructions for use of the medicinal product or medical device should be carefully read and a doctor or pharmacist should be consulted regarding the possible dose risk, and adverse reactions to the medicine or medical device.

In the message the warning should read: "Read the manual carefully before use! For indications, risk of use, and adverse reactions to the medicine or medical device, consult your doctor or pharmacist" and should be marked with a stronger colour in relation to the other part of the message, in a frame of at least one tenth of the size of the message, written in a letter size that allows it to be normally visible and not overlooked.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

The Law on Medicinal Products and Medical Devices prohibits the advertising of prescription-only medicines to the general public through the media.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

As an exemption to the prohibition described in question 6.2, and for the purpose of protecting the public health or preventing extraordinary situations (epidemic, larger-scale natural disasters, etc.), the director of the Macedonian Agency for Medicines and Medical Devices, upon a proposal of the Committee for Medicinal Products, may allow advertising in the media aimed at providing information to a wider public regarding the use of certain medicinal products.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

The prohibition as described in the answer to question 6.2 above shall apply to all types of media directed at the general public.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Bearing in mind that pharmaceutical advertising must be approved prior to publishing, and as corporate brochures/annual reports may be publicly available (to the general public), depending on the legal form of the company, including information on products shall be acceptable if such information is not intended to advertise such pharmaceuticals. Providing information with regards to the quantity of production or sales should not be considered advertising.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There are no specific rules, which apply to meeting with and funding patient organisations.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

There is no general prohibition as to such activity. However, it must be noted that dispensing medicine samples to the general public is prohibited.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

In accordance with the Law on Medicinal Products and Medical Devices, the applicant for a clinical trial is responsible for the implementation of the trial and for the course of the clinical trial, and is obligated to submit a report to the Macedonian Agency for Medicines and Medical Devices, every three months as well as to submit a final report for the results of the clinical trial of the medicinal product, within one year as of the day of concluding the clinical trial of the medicinal product.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

In accordance with the Law on Medical Products and Medical Devices, upon advertising medicinal products, marketing authorisation holders or legal entities and natural persons acting on their behalf shall not offer gifts, direct or indirect financial or material benefit to persons who prescribe or dispense medicinal products, except those of small value and intended for performing healthcare activities.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Please see the answer to question 7.2 above.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Please see the answer to question 7.2 above.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, the advertising of a medicine or medical device can be performed through advertising in the public media, via the Internet, advertising on public places and other types of advertising intended for the general public.

The prohibition on advertising prescription medicines also applies to advertising via the Internet.

If the advertising of the medicine or the medical device is carried out via the Internet, the message which must be included in all types of medical advertisements ("Read the manual carefully before use! For indications, risk of use, and adverse reactions to the medicine or the medical device, consult your doctor or pharmacist") should be an integral part of the initial, i.e. the main page of the Internet message from the advertisement, and not the page which is given as a link, i.e. the reference to the main page.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

If the advertisement is intended for the expert public, the holder of the authorisation shall limit the access to information only to the persons referred to as the "expert public" in the Guidelines on the manner of advertising of medicinal products and medicinal devices ("*expert public, means all health workers who prescribe, sell, or issue medicine or medical devices, which purchase the medicine i.e. medical device for pharmacies, that is, for the specialised stores for other healthcare institutions, or in any other way affect the procurement and use of the medicinal products i.e. medical devices, graduated pharmacists and others professionals involved in the production and marketing of medicinal products i.e. medical devices wholesalers and retailers, as well as professional employees of the Ministry of Health and the Macedonian Agency for medicines and Medical Devices*").

However, there are no special provisions as to the level of security required in order to insure that the general public does not have access to websites or data on websites intended for the expert public. With this in mind, at this time, unfortunately, the restriction application is left to the conscientiousness of the companies.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

If any such content published on company-related/sponsored sites is considered in breach of legislation, competent authorities may order such content to be removed. The company may be held responsible for any advertising in breach of positive legislation governing the advertisement of medicinal products as well as advertising in general.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

A company may provide general data relating to a company's name, address, legal form, etc. Any information published should be truthful and correct and not in breach with positive legislation. In connection to pharmaceutical advertisement, the general rules apply.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no specific rules, laws or guidance controlling the use of social media as of this moment. However, it should be noted that the general rules for advertising apply to advertising on social media as well.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

There have not been any legislation changes regarding the advertising of medicinal products and devices in the past year.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

New laws governing medicinal products, medicinal devices and pharmacies should be adopted by the end of 2019, mainly for the purposes of aligning with the European Union regulative and following modern trends in regulation with the pharmaceutical industry.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

There have not been any general practice or enforcement trends that have become apparent over the last year.

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DDK
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ATTORNEYS AT LAW

Accepting the premise that no one can be equally versed in all fields of law, Debarliev, Dameski & Kelesoska Attorneys at Law (DDK) has been created as a company committed to be the leading business law firm in the Republic of North Macedonia.

Debarliev, Dameski & Kelesoska Attorneys at Law is also the first law company established in the territory of the Republic of North Macedonia, distinguishing itself in the market with a clear business and corporate law orientation, complemented by an excellent network of legal experts covering the complete territory of the Republic of North Macedonia.

The quality of Debarliev, Dameski & Kelesoska Attorneys at Law rests mainly upon the quality of its attorneys, their accessibility and efficiency. DDK's attorneys at law share outstanding academic backgrounds, as well as a strong commitment to legal perfection.

The partners at DDK have more than 20 years' law practice experience and have exceeded clients' expectations by providing sophisticated and efficiently managed legal services.

DDK offers excellent legal services to clients involved in all of the biggest M&A and energy projects in the Republic of North Macedonia, and has been engaged as counsel in numerous successful PPP projects, privatisations, capital markets transactions, banking, joint ventures, etc.

# Mexico

José Alejandro Luna Fandiño

OLIVARES

Armando Arenas Reyes

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The primary legislation for the advertising of medicinal products is the General Health Law (*Ley General de Salud*) (HL), and its Regulations (*Reglamento de la LGS en materia de Publicidad*) (HLR). These norms are supplemented by guidelines published by the Regulatory Agency, the Federal Commission for Protection against Sanitary Risks (COFEPRIS). This agency is part of the Ministry of Health and controls the advertising of medicinal products.

Industry Codes of Practices complement this regulation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments (the Codes):

- The Code of Ethics and Transparency of the Pharmaceutical Industry (Code of Ethics & Transparency).
- The Code of Good Practices of Promotion (Code of GPP).
- The Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organisations (Code of GPI).

The latest versions of these Codes have been in force since April 1, 2013. Affiliate members of the National Chamber of the Pharmaceutical Industry (CANIFARMA) are required to follow these Codes. CETIFARMA supervises members' and adherents' compliance.

There are also opinions issued by the Advertising Council, which include representatives from the Ministry of Health, the academic and scientific communities, the business sector, the media and consumer groups.

Additionally, other general legislation may be relevant for the advertising of medicinal products, particularly, the Federal Law for the Protection of Consumers and the Industrial Property Law.

### 1.2 How is "advertising" defined?

Article 2 of the HLR defines advertising as, "*the activity comprehending any process of creation, planning, execution, and circulation of ads in media channels which aims to promote the sales or consumption of products and services*".

An advert is, according to this Article, "*the message directed to the public or a section of the same, with the purpose of informing about the existence or characteristics of a product, service or activity for its commercialisation and sale or to motivate a conduct*".

For the Code of GPP, promotion means any activity undertaken, organised or sponsored by a pharmaceutical company or under its authority (subsidiaries, foundations, associations, institutes, agencies, etc.) which supports the prescription, dispensing, sale and acquisition or administration of its medicines, complying with applicable rules, regulations and standards.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The Code of Ethics & Transparency requires members to strictly comply with the applicable legal provisions, and their personnel to have at least a broad knowledge of all of the applicable provisions.

Concerning advertising and promotional activities, the above Code requires them to give accurate and objective explanations on the characteristics, functions, advantages or disadvantages of their products or services.

The Code of GPP requires that the information provided to healthcare professionals is accurate, balanced, fair and objective, and sufficiently complete to enable them to form their own opinion of the therapeutic value of the medicine.

Under no circumstances can promotional material be distributed in a final version, to which no further amendments will be made, if it has not been certified and authorised by the medical authorities of the laboratory and the person in charge of confirming its compliance with the Codes. These authorities must certify that the material's final form has been examined: that it abides by the provisions of the Code of GPP and by the applicable standards on advertising practices; and that it complies with commercial authorisations and, in particular, with the information of the marketing authorisation in effect. Presentations must be true and faithful to the medicine's stated characteristics.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

The Code of Ethics & Transparency requires members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation. In this regard, members are required to establish the proper measures and monitoring procedures to verify that their associated members abide by the regulations applied to the different activities they perform.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

Article 79 of the HLR sets forth that the advertisement of medicinal products must be approved. Approval applications should be filed before COFEPRIS. These applications must include all of the characteristics of the intended advertising.

There is also the possibility of submitting only a notice rather than an approval application when the advertising is only directed to healthcare professionals.

The regulations allow companies to have a previous opinion by an authorised expert. This opinion may be filed along with the approval application to speed up the process.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

COFEPRIS has specific authority to order the suspension of an advertising activity in breach of legal framework. This order has to be followed by both the responsible party and the media channel within a term of 24 hours.

COFEPRIS may warn companies with approved products to modify ads which are presumably in breach of the legal framework. If not modified, or the modification is considered to not comply with the legal provisions, COFEPRIS may suspend the advertising activities and impose a fine.

The decision and orders issued by COFEPRIS may be appealed before itself or the Federal Courts.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The penalties for failing to comply with the rules related to advertising are the suspension of advertising activities ordered either to the responsible party or directly to the media, and the imposition of a fine to each one, which can range from 2,000 to 16,000 minimum wages (around 9,000.00 USD to 73,000.00 USD). The responsibility for imposing these penalties falls directly on the Ministry of Health, through COFEPRIS.

Regarding the strictness on the imposition of these fines, in our experience it has been steadily increasing. COFEPRIS constantly monitors advertising activities throughout the country, particularly regarding drug-like products. COFEPRIS has been directing the efforts of coordination agreements related to publicity, and the enforcement of the same.

There has also been a strong coordinated effort between COFEPRIS and pharmaceutical companies tending to the self-regulation of advertising, which is still monitored.

As for any important examples where action has been taken against over-the-counter pharmaceutical companies, it is worth mentioning that COFEPRIS has imposed large fines against specific over-the-counter medication manufacturers for using misleading advertising related to its products, inciting the public to self-medicate and taking their products at the first symptom without consulting a doctor.

Regarding the possibilities for competitors to take direct actions related to advertising infringements, the General Health Law and the Regulations of the Health Law regarding advertising, both contemplate the possibility of a so-called "people's action", which is a complaint filed before COFEPRIS regarding a breach of the provisions of the law. Issues related to unfair competition will be directly addressed in question 1.9 below.

The Industry Code of Practice empowers CETIFARMA to supervise and impose monetary sanctions to members in breach of these Codes.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

COFEPRIS's supervisory and enforcement functions are supplemented by the Codes enforced by CETIFARMA. This self-regulatory process, therefore, does not preclude the statutory powers of COFEPRIS, which, at its discretion, may or may not take into account findings from the self-regulatory body.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Actions based on unfair competition derived from advertising activities can be taken based on the provisions set forth by the Industrial Property Law.

Actions can be brought before the Mexican Institute of Industrial Property (IMPI) either by the directly affected party or by the authority itself.

If there is a firm unfair competition decision, the affected party can claim damages and lost profits before a civil court.

Additionally, Article 32 of the Federal Law for Consumer Protection establishes the possibility of filing a complaint before the Bureau of Consumer Protection (PROFECO) regarding false or tendentious advertising, which can impose a fine to the responsible party and order to stop the specific advertising activities.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

According to Article 42 of the HLR, prescribing information about products to healthcare professionals is subject to approval before publication. This information is approved while granting marketing authorisation for the corresponding product. Any publication should have the marketing authorisation number of this product.

The Code of GPP sets forth that information about medicinal products must be grounded on scientific evaluation and related empirical evidence, which must be kept at the disposal of healthcare professionals, if required. It must not induce confusion by means of distortion, unjustified pressure, omission or any other means.

This Code also states that, when scientific information is provided and is not part of the prescribing information duly approved or authorised in the marketing authorisation of a product, it should be strictly limited to a scientific audience, avoiding the promotion, directly, indirectly or through a third party, of any unauthorised directions of use.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

With respect to results of clinical trials, the Code of GPP sets forth that when they are being published in specialised or widespread distribution magazines, pharmaceutical companies have to request the disclosure of any conflicts of interest from the authors.

With respect to scientific information that is not part of the prescribing information duly approved or authorised in the marketing authorisation of a product (off-label information), this Code requires that providing this information must be strictly limited to a scientific audience, avoiding the promotion, directly, indirectly or through a third party, of any unauthorised directions of use.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

According to the HLR, any advertising of medicinal products to the public should be approved by COFEPRIS. The product must have a marketing authorisation. The Code of Ethics & Transparency requires members to promote responsible prescription and discourage self-medication. It should be analysed, therefore, on a case-by-case basis, whether a press release is or is not an advertising activity.

The Code of GPP states that, when a company, directly or indirectly, finances, sponsors or organises the publication of promotional materials in journals or magazines, it must be expressly stated that the material is not presented as an independent editorial matter and the sponsorship of the company must be clearly displayed.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

As mentioned above, the Code of GPP sets forth that information of medicinal products must be grounded on scientific evaluation and related empirical evidence, which must be kept at the disposal of healthcare professionals, if required.

When scientific information is provided that is not part of the prescribing information duly approved or authorised in the marketing authorisation of a product, it should be strictly limited to a scientific audience, avoiding the promotion, directly, indirectly or through a third party, of any unauthorised directions of use.

**2.5 How has the ECJ judgment in the Ludwigs case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The above case law is not relevant to Mexico, as it is not an EU Member State.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

With respect to private institutions, it is advisable to first obtain the medicine's approval before sending them information, in order to avoid this being perceived as advertising of an unauthorised medicine.

With respect to public institutions, they have to follow the National Formulary (*Cuadro Básico de Insumos para la Salud*) that is issued by the Ministry of Health. This is essentially a list of products that can be acquired by public insurers. To have a product listed in this formulary it is required to have been approved, among other requirements.

Such products are acquired mainly through public tender processes, unless they have to be directly acquired from exclusive rights holders, for example, in the case of patented products.

The Code of Ethics & Transparency requires members to fully and loyally comply with the precepts of the legal framework applicable to public tender processes. The Code mandates that during the acquisition process, through public bidding or any other procedure of government acquisition, there should be no attempt to either exert undue influence upon the decision-making process, or to gather confidential information from government officials acting on behalf of a government office or entity.

In addition, the Committee for the Negotiation of Drug Prices (CNDP) supports public acquisitions through a process of transparent negotiation between public insurers and pharmaceutical companies, particularly regarding patented products. The Committee evaluates the cost-benefits of new medicines and therapies in view of other comparable products in the market.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The Code of GPP allows accredited healthcare professionals to be hired to participate in clinical trial studies and other research. The Code states that under no circumstances can healthcare professionals, whatever their accreditation, be hired in order to induce the use, prescription (products and/or indications), purchase or recommendation of a specific product or to influence the results of a clinical study. The standards mentioned below in question 5.4 would also apply.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

According to Article 42 of the HLR, advertisements directed to healthcare professionals can only be published in specialised media, and they must be based on the approved prescription information of the corresponding medicinal product.

However, in December 2017, COFEPRIS issued new guidelines regarding the advertising of prescription-only medicinal products. According to these guidelines, prescription-only medicinal products that can be purchased as many times as prescribed, can now be advertised in mass media, provided that these advertisements are transmitted within specialised programmes, informative capsules or their advertising breaks, which should be aimed at professionals, technicians and auxiliaries of the health disciplines, or in another type of programming and/or means of communication, as long as it complies with the following characteristics:

- That within the advertising message there is a strong message that speaks of the consequences of self-prescription and microbial resistance, which should have an approximate duration of 10%–20% of the entire advertising message.
- Knowledge of innovative or generic medicines should be promoted.
- A caption should be included that says: "Exclusive information for health professionals, avoid self-medication" in accordance with the provisions of Article 10 of the HLR.
- Advertising on television or in electronic media must contain the following caption: "*The use of this medicine requires a prescription*" and must include at least one of the following disclaimers: "*The improper and excessive use of antibiotics generates resistance and puts your health at risk*", "*Only use antibiotics when a health professional prescribes it*", "*Never use antibiotics that you have left over and do not share them with others*", "*Always take the complete prescription, even when you feel better*", "*Doctor: Prescribe and dispense antibiotics only when needed*".
- The advertising notice must be made five days prior to its dissemination in any means of communication for the purpose that during that period the COFEPRIS will give its approval.

The Code of GPP states that the relationships between pharmaceutical industry personnel and healthcare professionals should encourage the development of a medical practice committed to patients' well-being, based on truthful and accurate information and tested and up-to-date scientific evidence in order to contribute to the appropriate use of approved medicines.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

The Code of GPP requires that the medical and scientific departments of its members ensure that the information provided to healthcare professionals is accurate, balanced, fair and objective, and sufficiently complete to enable the recipients to form their own opinion of the therapeutic value of the medicine.

Members must take scientific and moral responsibility for the content of the information provided by them, or others by an agreement (outsourcing).

According to the Code of GPP, when promotional material refers to published studies, these must be faithfully reproduced or clear, easily accessible references must be given. A faithful reproduction is one that reflects the full meaning and content of the original source in an objective manner, without adding or excluding any information that could mislead or confuse the recipient.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

The Code of Ethics & Transparency requires members to refrain from taking undue advantage of their clients, or any product, individual, company, commercial brand or symbol, through mass media advertising.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There is no specific provision referring to head to head clinical trial data before comparative claims, however, the Code of GPP states that the information must be grounded on scientific evaluation and related empirical evidence, which must be kept at the disposal of healthcare professionals, if required. It must not induce confusion by means of distortion, unjustified pressure, omission or any other means.

As mentioned above, when promotional material refers to published studies, these must be faithfully reproduced or clear, easily accessible references must be given. A faithful reproduction is one that reflects the full meaning and content of the original source in an objective manner, without adding or excluding any information that could mislead or confuse the recipient.

As an example of this, when the effectiveness and safety of different active principles are compared for advertising purposes, information such as the statistical appraisal of the results must not be omitted. Statistics, conclusions or any other data derived from different studies using different methodologies, must not be mixed or compared, unless resulting from systematic reviews or meta-analysis where the homogeneity criteria is specified. Adaptations that may introduce bias or confusion are unacceptable.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

In December 2017, COFEPRIS issued new guidelines regarding the approval of ads for non-prescription medicinal products, where it is indicated that comparisons between medicines or active ingredients that have the same therapeutic purpose are valid as long as they do not demerit or present competitors in a situation of inferiority, adding that the comparisons should not question the quality of products that have marketing authorisation, no veiled or express comparisons are allowed with products of a different nature to the type of product to be advertised.

Comparative advertisements are further contemplated in both the Industrial Property Law and the Federal Law for the Protection of Consumers. Both of these laws contain provisions related to actions that can be filed against the party responsible for the comparative advertisement.

According to Article 213 subsection X of the Industrial Property Law, it is possible to use another company's brand name in advertising as long as the comparison is intended to inform the public, and it is not tendentious, false or exaggerated.

Article 32 of the Federal Law for the Protection of Consumers also penalises unfair practices in comparative advertisements, including unfair use of trademarks, and contemplates the possibility of filing a complaint before the Consumer's Bureau for such activities.

The Code of Ethics & Transparency calls members to compete fairly, avoiding unfair practices. Market competition must be fair and respect intellectual rights, or any other member's rights.

The above Code requires members to refrain from discrediting competitors or spreading any false or inaccurate information about their activities or products. The Code of GPP states that claims or comparisons while providing information shall not be included unless scientifically tested. All information, claims or comparisons included in promotional material must be substantiated and fair. In particular, any comparison between different medicines must be scientifically sustained and must comply with the regulations of fair competition standards. It must not be denigrating and comparisons must be grounded on equivalent elements and relevant evidence.

As to the referral to a competitor's product that has not been approved in Mexico, there are no clear specific provisions in this regard, provided that it does not have a well-known trademark in Mexico. Thus, our recommendation would be to submit the ad before COFEPRIS for an opinion or an authorisation, in order for it to determine whether the ad implies a risk to public health.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The Code of GPP sets forth guidelines for these activities. Public institutions may have their own particular guidelines.

The Code states that congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by pharmaceutical companies or any other third party must have, as a main purpose: scientific exchange; medical education; and/or information about medicines.

Whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily, to improve their knowledge of patient care. In each case, programmes must comply with the guidelines of the applicable laws: they must have strict scientific content sustained, if required, on clinical evidence; and, most importantly, they must be accredited and certified by the corresponding academic authorities.

Support in general will not be offered, under any circumstance, in order to have any kind of influence on the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Although there is no legal provision specifically forbidding teaser ads of medicinal products, the Code of Ethics & Transparency requires members, while providing information or advertising, to give accurate and objective explanations on the characteristics, functions, and advantages or disadvantages of the products or services.

In addition, the Code of GPP mandates that all promotional material, including advertising in printed, audio-visual or electronic media, must be legible and in strict accordance with the terms established in the marketing authorisation and with the ethical principles included in the Codes.

Therefore, there is a chance that teaser ads would be considered in breach of the Codes, as information to healthcare professionals must not induce confusion by means of distortion, unjustified pressure, omission or any other means and could be considered as misleading for the consumers.

Additionally, promotional activities to consumers should inform the patient or consumer about the properties of the medicines he/she is using, of the importance of concluding the treatment prescribed by the physician, and about the risks of substituting the prescribed medicine for another one without knowledge and proper medical supervision.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Provided that the indication for the combination use was expressly authorised for Product A, the holder of the MA for Product A can certainly rely on the approved use of Product B with Product A in Product A's SmPC to promote the combination use. However, the holder of Product B cannot promote such combination use until expressly authorised in the SmPC for Product B.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes. According to the Code of GPP, samples are provided directly to healthcare professionals in fair amounts and without cost in order to support the medical treatment, so that they may get to know and be familiar with the product.

According to Article 49 of the HLR, providing samples of products for free does not require approval, provided that they meet the requirements of the approved medicinal product. These samples should be contained in a package with a lesser number of units than the approved product.

Sampling of prescription-only medicinal products is not permitted to the general public. Any sample of a medicinal product must not be given out to minors. Samples must also contain the wording "*Not for sale*".

The Code of GPP establishes guidelines for sampling. It prohibits members from offering or supplying samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples.

In addition, according to Article 464 *ter* of the HLR, the sale of medical samples is a crime punishable with one to nine years in prison and a fine equivalent to between 81,746.00 USD and 204,355.00 USD.

Members are required to have full and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians.

We always recommend that our clients have strict control on product samples since there have been cases where said samples have been re-sold.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

The Code of GPP essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value may be offered to healthcare professionals, or incentives of any kind, as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study.

No gifts, bonuses, pecuniary advantages, benefits in kind, or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional aids related to the practice of medical or pharmaceutical activities.

The Code delineates as inexpensive promotional aid that one that does not exceed the equivalent of 10 times the minimum wage (around 40.00 USD).

The Code allows pharmaceutical companies to grant financial aid or scholarships to a healthcare professional in order to attend scientific or educational events, in accordance with the health institutions where the professional develops their activities.

Under no circumstances will funding be offered to induce healthcare professionals to use, prescribe, buy or recommend a specific product, or to influence the results of a clinical study. The same criteria may be applied to independent educational programme funding.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Donations are part of the promotional, socially responsible activities of companies, according to the Code of Ethics & Transparency. These would be granted to non-profit organisations and institutions in order to support altruistic and social projects, as long as they refrain from using donations as a means to promote products from the donor companies.

The Code of GPP states that donations of medical equipment must not be associated with promotional practices; instead they must be properly channelled through the corresponding institution and they must not be made in a personal capacity.

According to their guidelines, companies will make available to the public, information concerning the donations granted in order to promote transparency.

In Mexico there is not a specific monetary limit regarding donations, but donations must comply with the formalities established in the Mexican legislation, specifically the Mexican Tax Regulation.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The Code of GPP states that the provision of objects such as books or material on optical, magnetic and electronic support, and scientific material is acceptable provided their commercial value does not exceed the equivalent of 50 minimum wages overall (around 200.00 USD). The provision of any good or service of any kind, however, should not be for the inducement to use, prescribe, purchase or recommend a specific product.

According to the Code, promotional activities directed to healthcare professionals, therefore, should only help them to sustain their therapeutic decisions.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

The CNDP mentioned above is a price-negotiating commission formed by several public offices (including major institutes of health) which negotiates prices for drugs with single manufacturers (such as drugs under patent rights) where prices are reduced through volume acquisitions. The offer of discounts in these negotiations is permitted and encouraged.

As far as we know there are no specific rules for this sort of practice regarding the private sector. Even though discounts could have implications derived from our anti-trust law, several conditions, such as relevant market power, would have to coincide before a violation to the provisions of this law takes place.

Additionally, the Code of Ethics & Transparency prohibits members: making arrangements with competitors to manipulate or increase price levels, potential markets, territories or client distribution; restricting or conditioning production; impeding distribution or commercialisation channels; or encouraging the exclusion of any product from sale points.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

The HLR states that the advertising of medicinal products cannot be approved when it promotes consumption of those in exchange for another product or service.

We have participated as advisors in cases where COFEPRIS objects to corporate advertising, arguing that programmes related to providing additional medical or technical services or equipment is a violation of provisions in the health law. Several modifications to the terms of the advertisements were made as a consequence of objections by the authority.

However, in December 2017, COFEPRIS issued new guidelines regarding the approval of ads for medicinal products, where it is indicated that offers and promotions may be made to the final consumer or users of non-prescription medicinal products, where although its application is not clear under this assumption, it provides that it is possible to offer packages of medicines and hygienic products or medical devices whose sale does not require a medical prescription and are considered as low risk for purposes of obtaining a marketing authorisation, or those that due to their nature, characteristics and use are not considered as health supplies and do not require marketing authorisation and have the same therapeutic purpose, contribute to the relief of a symptom or common health problem of the final consumer and are directed to the same age group.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Patient access schemes/patient adherence programmes are not broadly developed in the Mexican legal framework. Companies such as Pfizer, Novartis and GSK have implemented their own patient adherence programmes.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

As mentioned above, the Code of GPP states that whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily, to improve their knowledge of patient care. In each case, programmes must: comply with the guidelines of the applicable laws; have strict scientific content sustained, if required, on clinical evidence; and, most importantly, be accredited and certified by the corresponding academic authorities.

Support, in general, will not be offered under any circumstances in order to have any kind of influence on the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

According to the above Code, funding and support in kind, granted by the pharmaceutical industry for continuous educational medical programmes, must be exclusively designated for scientific and academic purposes.

Pharmaceutical companies may grant financial aid or scholarships to enable a healthcare professional to attend scientific or educational programmes, in accordance with the health institutions where these professionals develop their activities.

Under no circumstances will funding be offered to induce healthcare professionals to use, prescribe, buy or recommend a specific product, or to influence the results of a clinical study. The same criteria may be applied to independent educational programme funding.

Members must notify CETIFARMA of these events, in due form, at least two months prior to the event.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

On July 18, 2016, several decrees were enacted in accordance with a Constitutional Amendment for Anti-bribery Matters in Mexico. These decrees were aimed at implementing, amending and supplementing various laws and acts, which together comprise the new National Anti-Corruption System.

The main mandatory anti-bribery rules and provisions currently in place applicable to private parties, whether individuals or corporations (including pharmaceutical companies), are contained in: (i) the Mexican Federal Constitution; (ii) the Federal Anticorruption Law for Government Procurement; (iii) the Federal Criminal Code; and (iv) the international anti-corruption conventions as to which Mexico is a party (the United Nations Convention Against Corruption, the Inter-American Convention Against Corruption and the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions).

As of July 19, 2017, the General Act of Administrative Responsibilities (GAAR) will enter in force in Mexico, repealing the Federal Anticorruption Law for Government Procurement. The GAAR sanctions, among other corrupt activities, the acts of private parties related to administrative liabilities when interacting with public officials, such as bribery, illegal participation in administrative procedures, influence peddling, collusion and undue contracting of former public officials. Some of the main administrative liabilities considered under the GAAR include the disqualification from public acquisitions for no less than three months and no more than 10 years, and the suspension of activities for no less than three months and no more than three years.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The Code of GPP allows members to provide proper hospitality to healthcare professionals, medical researchers or experts participating in events. This should not be extended to persons who are not involved with the corresponding event, thus, they would not be provided with financial aid or any other kind of support.

According to the Code, the concept of proper hospitality includes the reasonable cost or payment of round-trip travel expenses, lodging and meals and eventual registration fees. CETIFARMA may determine whether the hospitality is reusable according to its standards.

The Code prohibits organising or sponsoring events outside the country that are directed to healthcare professionals residing in Mexico, unless:

a) More than 80% of the invited healthcare professionals come from abroad and the prospective venue is more convenient for the majority of the participants.

b) Justified motives exist in terms of security or costs.

In these cases, the Code must be respected, as well as the specific legal provisions applied by the host country.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

According to the Code of GPP, members may grant financial aid or scholarships to healthcare professionals in order for them to attend scientific or educational events, in accordance with the health institutions where these professionals develop their activities.

As mentioned above, hospitality means the reasonable cost or payment of round-trip travel expenses, lodging and meals and eventual registration fees.

Members will only pay for reasonable out-of-pocket expenses incurred individually by a consultant attending a scientific conference or a third party's meeting in their capacity as a healthcare professional or in representation of a member. Under no circumstances can healthcare professionals, whatever their accreditation, be contracted in order to induce the use, prescription, purchase or recommendation of a specific product or to influence the results of a clinical study.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

The Code of GPP holds members responsible for verifying that the events they support are in compliance with the Codes. CETIFARMA may supervise this compliance and sanction breaches to the Codes.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

The Code of GPP states that accredited healthcare professionals may be contracted on a consultancy basis to provide their support and scientific knowledge, such as: helping in the development of medical products; participating in clinical studies or other research; and giving lectures or presentations to the sales departments, in meetings, or to train laboratory staff.

Remuneration to healthcare professionals must not exceed the market value of the services provided. The location and circumstances of a consultants' meeting must be consistent with the consultancy services provided.

Government employees or staff from regulatory bodies must not be assigned for consultancy services when a conflict of interest is involved.

Pharmaceutical companies must compel healthcare professionals contracted as consultants to disclose this activity, to avoid conflicts of interest.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

As mentioned above, the Code of GPP allows the hiring of accredited healthcare professionals to participate in clinical trial studies and other research. The standards mentioned above in question 5.4 would apply.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

As mentioned above, the Code of GPP allows the hiring of accredited healthcare professionals to participate in clinical trial studies and other research. The standards mentioned above in question 5.4 would apply.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, but subject to approval by COFEPRIS. Pursuant to Article 43 of the HLR, any visual or audio advertisement must bear the following message: "*Consult your physician*". Advertisements should mention applicable precautions, and when the use of the medicine represents any danger in the event of an existing pathology.

The Code of GPP requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.

As mentioned above, in February 2014 COFEPRIS issued detailed guidelines regarding the approval of ads for non-prescription medicinal products.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Pursuant to Article 310 of the HL, only non-prescription medicines can be advertised to the general public, and the objective of said advertisements is to inform the public about the characteristics of the products, their therapeutic properties and the form of use.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

The Code of GPP states that promotional campaigns should tend to:

- Discourage self-prescription and product recommendations among consumers.
- Promote respect for a physician's prescription in terms of proper dosages and methods of use.
- Respect the procurement and supply procedures of prescription medicines, if required by law.
- Respect a physician's prescription of a specific product, in such a way that a pharmacy employee is not induced to modify it for the benefit of a particular company.
- Inform patients/consumers about the properties of the medicines they are using, the importance of concluding the treatment prescribed by a physician, and about the risks of substituting the prescribed medicine for another one, without knowledge and proper medical supervision.
- Appoint a person responsible for pharmacovigilance matters in order to compile, collect and analyse all of the information provided by medical representatives, or any other source, concerning the doubts and side effects of the medicines they commercialise.

COFEPRIS's advertisement guidelines state that this regulatory agency will not approve an ad providing disease awareness to be followed by another ad of an over-the-counter medicinal product related to that disease, unless both ads are approved jointly.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

The Code of Ethics & Transparency requires members to promote responsible prescription and discourage self-medication. It should be analysed, therefore, on a case-by-case basis, whether or not a press release for a prescription-only medicine is an advertisement activity.

In December 2017, COFEPRIS issued new guidelines regarding the advertising of prescription-only medicinal products. According to these guidelines, prescription-only medicinal products that can be purchased as many times as prescribed, can now be advertised in mass media, provided that these advertisements are transmitted within specialised programmes, informative capsules or their advertising breaks, which should be focused for professionals, technicians and auxiliaries of the health disciplines, or in another type of programming and/or medium, as long as it complies with the applicable requirements.

The Code of GPP states that material related to medicines and their uses, whether promotional or not, which is sponsored by a pharmaceutical company, must clearly indicate that it has been sponsored by that company.

According to the Code of GPP, in Mexico it is possible for a press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

There are no specific legal or code provisions in this regard. Members are responsible, however, for verifying that their brochures/reports are, in general terms, in line with the Codes. CETIFARMA may supervise this compliance and sanction breaches to the Codes.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

The Code of GPP establishes that collaboration between the pharmaceutical industry and patient organisations must have a written agreement in place which will include, at least:

- the activities to be undertaken, and the cost, source and destination of funding; and
- direct and indirect support and any other relevant non-financial aid.

In these agreements, members have to follow their applicable guidelines, codes of ethics and conduct, their transparent practices and the deontological instruments approved by CETIFARMA and CANIFARMA.

The Code requires members to set forth criteria and procedures for the approval and implementation of these kinds of collaborations.

Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The Code of GPP states that in no case can health professionals be offered items with significant monetary value or incentives of any kind to use, prescribe, purchase or recommend a product or influence the outcome of a clinical trial. The delivery of objects such as books or materials on optical, magnetic, electronic and scientific equipment are excluded from this, if the secured value of these articles as a whole is less than 50 daily minimum wages equivalent to 200.00 USD.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The Code of GPP, which is a self-regulatory code of practice, requires members to publish positive and negative research results, particularly concerning adverse side effects. They should ensure the protection of participants' data according to applicable norms.

When results are being published in specialised or widespread distribution magazines, pharmaceutical companies will request that authors disclose the presence or absence of any conflicts of interest.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

The Codes of GPP and GPI allow CETIFARMA to require members to record any valuable support given to healthcare professionals, institutions or patient organisations. According to their guidelines, members will provide information concerning donations granted available to the public on a yearly basis in order to promote transparency.

Such requirements apply only to CETIFARMA's members, regardless of if they have been granted a marketing authorisation or not, or if they are foreign companies.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Please see the answer to question 7.2 above.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

The interactions of the pharmaceutical industry with health professionals can generate conflicts of interest, as well as supporting studies, invitations to conferences and other promotional activities. In order to face these situations which may create doubts or uncertainties, the CETIFARMA should be consulted, so that in the scope of their capacity and in adherence to the Code of Ethics and current regulations, they can advise and guide on the kind of behaviour to follow or apply.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

The Health Law Regulations apply to any advertising activity, including ads through electronic means and other forms of technological media.

COFEPRIS is in charge of monitoring ads on the internet. It has been strongly monitoring drug-like products, known as "miracle products" (products with non-proved health-related claims).

The Code of GPP states that the online promotion of prescription-only medicines addressed to healthcare professionals must be duly approved by the corresponding authorities. The advertising must be disclosed on scientific websites. The sponsor must be clearly identified.

Companies must adopt the proper measures to ensure the promotion of prescription medicines on their websites will only be accessible to healthcare professionals.

COFEPRIS issued guidelines for digital advertising that apply to any product subject to be monitored/approved by COFEPRIS. These guidelines clarify that digital advertising campaigns must be approved by COFEPRIS before being used on any digital media.

Recently, COFEPRIS issued new guidelines regarding the advertising of prescription-only medicinal products. According to these guidelines, prescription-only medicinal products that can be purchased as many times as prescribed, can now be advertised in mass media, provided that these advertisements are transmitted within specialised programmes, informative capsules or their advertising breaks, which should be focused on targeting professionals, technicians and auxiliaries of the health disciplines, or in another type of programming and/or means of communication, as long as it complies with the following characteristics:

- That within the advertising message there is a strong message that speaks of the consequences of self-prescription and microbial resistance, which should have an approximate duration of 10%–20% of the entire advertising message.
- Knowledge of innovative or generic medicines should be promoted.
- A caption should be included that says: "*Exclusive information for health professionals, avoid self-medication*" in accordance with the provisions of Article 10 of the HLR.
- Advertising on television or in electronic media must contain the following caption: "*The use of this medicine requires a prescription*" and must include at least one of the following disclaimers: "*The improper and excessive use of antibiotics generates resistance and puts your health at risk*", "*Only use antibiotics when a health professional prescribes it*", "*Never use antibiotics that you have left over and do not share them with others*", "*Always take the complete prescription, even when you feel better*", "*Doctor: Prescribe and dispense antibiotics only when needed*".
- The advertising notice must be made five days prior to its dissemination in any medium for the purpose that during that period the COFEPRIS will give its approval.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

The Code of GPP requires members to adopt the proper measures to ensure the promotion of prescription medicines on their websites will only be accessible to healthcare professionals. Such websites must have a precaution stating that it is only addressed to healthcare professionals empowered to prescribe drugs.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

There is no clear, specific provision in this regard. The Code of Ethics & Transparency, however, requires members to act in accordance with sound trading practices and in strict compliance

with the prevailing legislation. In this regard, members are required to establish the proper measures and monitoring procedures to verify that their associated members abide by the regulations applied to the different activities they perform.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

There is no clear, specific provision in this regard. As mentioned above:

- The Code of Ethics & Transparency requires members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation.
- The Code of GPP seeks to ensure transparency in the promotion of medicines and compliance with the ethical principles and the prevailing laws and regulations. This Code requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals who are authorised to prescribe.
- Members must adopt the proper measures to ensure the promotion of prescription medicines on their websites will only be accessible to healthcare professionals.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Recently, COFEPRIS issued guidelines for digital advertising that apply to any product subject to be monitored/approved by COFEPRIS. These guidelines clarify that digital advertising campaigns must be approved by COFEPRIS before being used on any digital media. They are required to have a community manager responsible for monitoring the content used in digital media and ensuring it complies with the approved one. However, these guidelines do not provide clear, specific provisions regarding medicinal products. Therefore, we advise to bear in mind that:

- The Code of Ethics & Transparency requires members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation.
- The Code of GPP seeks to ensure transparency in the promotion of medicines and compliance with the ethical principles and the prevailing laws and regulations. This Code requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.

Additionally, we recommend companies adopt the proper measures to ensure the promotion of prescription medicines through electronic means will only be accessible to healthcare professionals.

Conversely, mobile medical applications are a new area that COFEPRIS may address in the future with particular regulations, especially if they represent health risks.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

In December 2016, COFEPRIS signed the "Alliance for Digital Advertising" with the Mexican Association of Pharmaceutical Advertising Agencies (AMAPF), the Internet.mx Association and the Interactive Advertising Association (IABMX), with the objective of strengthening the Code of Ethics & Transparency and excluding any information that could mislead or confuse the recipient on the Internet.

The alliance will promote collaborative actions on digital advertising and encourage self-regulation, in favour of the final consumers of medicines.

Likewise, COFEPRIS has committed to promote the Code of Ethics & Transparency for the dissemination of pharmaceutical advertising, as well as promote and strengthen the population's access to objective information on the different products and services offered on the web.

COFEPRIS has strengthened the figure of Copy Advice as a free, voluntary, confidential and non-binding mechanism of pharmaceutical advertising, prior to the formal request for authorisation and dissemination, which has reduced time and will optimise resources for pharmaceutical industries.

In December 2017, COFEPRIS issued new guidelines regarding the advertising of prescription-only medicinal products. According to these guidelines, prescription-only medicinal products that can be purchased as many times as prescribed, can now be advertised in mass media, provided that these advertisements are transmitted within specialised programmes, informative capsules or their advertising breaks, which should be focused on targeting professionals, technicians and auxiliaries of the health disciplines, or in another type of programming and/or medium, as long as it complies with the applicable requirements.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

As a consequence of compliance practices, there is the expectation that the rules governing pharmaceutical advertisements will be strengthened by both industry associations and regulatory authorities.

On March 8, 2018, 11 countries signed the free trade agreement formerly known as the Trans-Pacific Partnership (TPP), which has been renamed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The signing members are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) includes several provisions that will certainly have a positive impact in terms of pharmaceutical advertising, particularly those included in the chapter for Regulatory Coherence and Intellectual Property.

On the other hand, Mexico, Canada and the United States of America signed on November 30, 2018 the United States–Mexico–Canada Agreement known as USMCA which also includes favourable amendments related to pharmaceuticals and regulatory matters and is expected to come into force by January 2020, provided it is ratified by all its signatories.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Since 2011, COFEPRIS has been targeting manufacturers of drug-like products, known as "miracle products" (which are not approved as medications and make health-related claims). Strong enforcement has been observed.

As of 2017, the Superior Chamber of the Federal Court of Administrative Justice has issued several judgments through which it has determined that the Specialised Court on Intellectual Property Matters is not competent to resolve appeals that are filed against acts issued by the Regulatory Agency, COFEPRIS, even when these are related to the protection of intellectual property rights, specifically in cases related to data protection and marketing authorisations, stating that these type of matters should be turned over to the Specialised Court on Environmental Matters and Regulation for its resolution. In this context and taking into consideration that COFEPRIS is the authority in charge of regulating the advertising of medicinal products, it is very likely that this criterion will also be applied to cases related to pharmaceutical advertising.


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Alejandro Luna joined Olivares in 1996 and became a partner in 2005. He is the Head of the Litigation & Regulatory practice group and Co-chair of the Life Sciences & Pharmaceutical law and industry group. Mr. Luna has been instrumental to the heart of Mexico's intellectual property legal system as an attorney, professor and lobbyist.

Mr. Luna has participated in questioning the constitutionality of certain provisions of the Industrial Property Law and the Federal Copyright Law. He is also the sponsor of an important proposal to modify the system of litigation and enforcement of intellectual property rights in Mexico. Mr. Luna has spearheaded a 10-year litigation strategy that has incorporated regulation changes and lobbying, which has resulted in precedent for patent linkage regulations and life terms of pipeline patents in Mexico. This work has resulted in billions of USD of protected revenues for the R&D pharmaceutical industry in Mexico. As a result of his involvement, Mr. Luna has been selected as the delegate to represent AMIFF, the industry association for R&D pharmaceutical companies that do business in Mexico, in the Trans-Pacific Partnership negotiations.

His commitment to just and fair law extends to his overall promise of client satisfaction; he lobbies to change the law to allow for proper patent protection and best serve his clients. Mr. Luna is also the author of several articles on patents, litigation and regulatory issues. He is a part-time professor at the Universidad Nacional Autonoma de México (UNAM).

**Professional qualifications**: Bachelor Degree, Universidad Latinoamericana 1996, Mexico; four diplomas, Universidad Panamericana; IP LL.M., Franklin Pierce Law Center 2002, US.

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**Languages**: English, Spanish.

**Recent publications**:

- *Getting the Deal Through: Life Sciences 2018*, Mexico Chapter, 2018.
- *ICLG to: Patents 2018*, Mexico Chapter, 2018.
- *ICLG to: Pharmaceutical Advertising 2017*, Mexico Chapter, 2017.
- *ICLG to: Pharmaceutical Advertising 2018*, Mexico Chapter, 2018.


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***Armando Arenas Reyes, Partner***

Armando Arenas joined Olivares in 2000 and became a partner in 2017. He has detailed regulatory expertise under Health Laws and provides strategic advice in complex patent litigation cases and dispute resolutions. His clients and deal experience include all segments of the industry – pharma, biotech, medtech, diagnostics, animal health, vaccines and health services.

He also represents life sciences companies before Mexican Courts handling the following relevant cases:

- Restoration of patents life term granted under provisions of article 12 Transitory (pipeline patents).
- Infringement actions of patents covering pharmaceutical products declared final and beyond appeal against generics companies.
- First case in Mexico where a marketing authorisation of a pharmaceutical product was revoked as the product violated a formulation patent listed in the *Linkage Gazette*.
- First case in Mexico of a use patent being effectively enforced in Mexico related to public tender.
- The unconstitutionality of article 167*bis* of the Health Supplies Regulation, as it does not provide the right of the titleholder of a patent to be heard during the prosecution of the marketing authorisation.
- First case in Mexico enforcing the linkage system so that the local regulatory agency considers a use patent included in the *Linkage Gazette* for allopathic medicines.

**Professional qualifications**: Mexico, Bachelor Degree by National Autonomous University of Mexico (UNAM), 1995.

**Areas of practice**: Pharmaceutical law, IP litigation and enforcement.

**Languages**: English, Spanish.

**Recent publications**:

- "COFEPRIS ordered to cancel marketing authorisation" *Managing Intellectual Property* [March, 2015].
- *Getting the Deal Through: Healthcare Enforcement & Litigation* 2015 and 2016.
- *Practical Law: Global Guides 2015/2016 Life Sciences*.
- *ICLG to: Pharmaceutical Advertising 2017*, Mexico Chapter, 2017.
- *ICLG to: Pharmaceutical Advertising 2018*, Mexico Chapter, 2018.

# Netherlands

Life Sciences Legal

Anke Heezius

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The following laws and codes of practice govern pharmaceutical advertising in the Netherlands:

- the Dutch Medicines Act;
- the Code of Conduct Advertising for Medicinal Products ("CGR Code"), supervised by the Foundation for the Code for Pharmaceutical Advertising ("CGR"); and
- the Code governing advertising of medicinal products to the general public.

### 1.2 How is "advertising" defined?

The Dutch Medicines Act defines advertising as "any form of influence with the apparent aim of promoting the prescription, supply or use of medicinal products, including any assignment thereto".

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

They must have:

- a scientific service, entrusted with the provision of information on the medicinal products brought to market; and
- an adequate internal procedure (SOP) for the disclosure of their financial relationships with healthcare professionals.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Yes, see question 1.3. The "scientific service" may be outsourced and the persons involved need to be "qualified", but the definition of "qualified", however, is not specified. The SOP needs to ensure that the disclosure of financial relationships is assessed in conformity with the CGR Code.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No, there is no requirement of prior approval. The self regulatory authorities may, however, give, upon request, non-binding advice on a proposed advertisement.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The Healthcare Inspectorate may forbid the use of the publication. Upon a complaint, the self regulatory authority or a court may order to stop the use of a certain advertisement and optionally order that a corrective statement is sent.

These decisions can be appealed.

### 1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Penalties of self-regulatory authorities include payment of procedural costs, up to €5,000, a rectification, and/or a recall of advertisements. The decision will be published. Competitors or other third parties may initiate complaint proceedings, and on average there are up to about 10 complaints a year at the self-regulatory authority for prescription medicines. Competitors may also directly initiate legal proceedings through the civil court; however, this option seems to be used on fewer occasions.

The Healthcare Inspectorate is responsible for the enforcement of the Dutch Medicines Act. It may impose administrative fines of up to €450,000 (or higher in the case of repeated violations). These penalties are not published, unless appealed at the administrative court, in the decision of the court. There are examples of action

taken, mainly against campaigns for the introduction of new medicines and advertising to the general public.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The Healthcare Inspectorate is responsible for the supervision of compliance with the Dutch Medicines Act. The self-regulatory authorities supervise compliance with the codes of conduct.

If a complaint is filed to the Healthcare Inspectorate, it will forward the complaint to the relevant self-regulatory body unless it is of the opinion that it concerns a sufficiently serious violation.

All decisions of CGR are sent to the Healthcare Inspectorate, who will monitor follow-up. Normally, it will not investigate the matter again.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Competitors can initiate legal proceedings in a civil court on the basis of unfair competition consisting of misleading advertising.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Providing information on off-label use towards prescribing healthcare practitioners is explicitly permitted. Likewise, it seems arguable that information about unregistered medicinal products is allowed as well, as long as the information does not contain any promotional claims, e.g. with regard to efficacy.

Sponsoring of an event is in principle not relevant in this context. But if an event is organised by a pharmaceutical company, it is presumed to have a promotional character (including all presentations), unless the scientific content of the meeting has been approved by the relevant self regulatory body in advance.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Yes, for instance, in a scientific journal (see question 2.1). Advertisements for an unauthorised medicinal product are, however, prohibited.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Yes, provided that the medicinal product, or its use, is not in any way being promoted or advertised (see question 2.2 above). Options to use media directed to the general public therefore seem limited, as highlighting one medicine may be considered as prohibited advertising to the general public.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

No, as that may readily constitute prohibited advertising of an unregistered product, it may only be sent upon a specific request.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Providing pricelists to pharmacists is allowed, as long as the information is limited to what is necessary for the purpose, and no additional (positive) information about the medicinal products is provided.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

It seems unlikely that such information can be sent to institutions for such purpose proactively and/or unsolicited, and as such may readily constitute prohibited advertising of an unregistered product.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Yes, this is possible, although a service agreement needs to be in place. Care should be taken so that no advertising takes place for the unauthorised product or indication. There are no specific guidelines.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Such advertisements must, *inter alia*, contain:

- information on the composition, therapeutic indications and contraindications, mode of action and adverse events of the product (information included in the abbreviated SmPC text);
- if the product is a self care product or a prescription product;
- the reimbursement status of the product; and
- the date of finalisation or last revision.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

The information, *inter alia*, may not conflict with the approved SmPC text or be misleading, and must be objective and encourage rational use of the product.

It may refer to scientific studies that are not mentioned in the SmPC, provided that the studies have been performed in accordance with the use and dosage prescribed by the SmPC.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Yes, such (unsupported) endorsements may not meet the requirement that the claims must be verifiably correct, i.e. must be supported by a written publication.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

No. Only a comparative claim must be substantiated by at least one "scientific study", that must have been published in a peer-reviewed journal, be of sufficient quality and sufficiently convincing. For this purpose, a head-to-head clinical trial seems to constitute the most solid basis.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

The CGR Code defines that the comparison must not be misleading. A brand name may be used but that company, its trade name, or the trade marks of the competitor's products must not be discredited, and no unfair advantage may be obtained as a consequence of the reputation of a trademark, trade name, or other characteristic of the competitor.

Reference to an unauthorised competitor's product in an advertisement is prohibited.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no specific rules, the general principles concerning the restrictions providing information to healthcare professionals apply (see section 2 and question 3.2 above). Pro-active handing of such documents by a pharmaceutical company will likely be considered as having a promotional purpose and therefore, the papers or proceedings must in such case, in principle, meet all the requirements of a promotional material.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Such teaser advertisements must be compliant with the requirement that each and every claim needs to be verifiably correct, i.e. it should demonstrate what is new and what that claim is based on.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

As no precedents are known, it is recommended to obtain legal advice in relation to a specific case. In general, an advertisement for a medicinal product may not in any way be contrary to its own approved SmPC. If Product A is approved for use in combination with Product B, Product A may likely be advertised for combined use. For Product B, the facts are different. The question then, is if the claim "approved for use in combination with Product A", is contrary to the SmPC of Product B, that does not contain that indication. Reference to the SmPC of Product A may not provide more legal certainty, as the advertisement may as a whole still be considered as an advertisement for Product B, that is to be in line with its (own) SmPC.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes, on the basis of a dated and personally signed request by a doctor, dentist or midwife. No new samples of the same medicinal product may be provided to a healthcare professional within two years of the request of the sample.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Gifts and donations of money are allowable, provided that they have a low value (with a maximum of €50 per gift and €150 per year, including VAT) and the gift or donation is useful for the professional practice and may not constitute a mere saving.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Giving gifts or donations of money to institutions with a higher

value than €50 per gift may be allowable as a form of sponsoring. This is permitted, provided that the support (a) involves innovative activities, (b) aims at the improvement of care to patients or the promotion of medical science, and (c) the sponsored activities concerned are not (fully) funded by other regular means (e.g. healthcare insurance). No monetary limits apply. Sponsoring must always be subject to a written agreement.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Yes, although the prescription behaviour may not be improperly affected. When gifts or services are provided to individual doctors, the hospitality norms apply (see question 4.2 above). The provision of sponsoring to organisations may not have a direct commercial purpose. If those requirements are met, any goodwill that is created by the goods or services is deemed acceptable.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Discounts in kind (provided that the bonus deliveries are of the same medicinal product) or in cash are possible, provided these are transparent, thus explicated especially on, for instance, an invoice or credit note.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

No, it is not allowed for a pharmaceutical company to offer or provide benefits in relation to the sale of its medicinal products, other than in kind, in the form of delivery of extra free-of-charge medicines as those that have been purchased, or in cash. In both cases, the benefit should be documented in writing.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

"Not satisfied money back" schemes are prohibited for non-prescription medicines in relation to the general public. In the context of a commercial transaction between institutions or pharmacies and pharmaceutical companies, it can, however, be imagined that a refund scheme is part thereof, provided that it can be defined sufficiently clearly when a medicinal prescription product does not "work".

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes, this qualifies as the provision of hospitality and is governed by the hospitality norms (see section 5 below). It is, *inter alia*, required that any liaisons between speakers and industry are disclosed prior to a presentation via a standard disclosure slide.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

It is, in brief, prohibited to offer gifts to employees with the purpose of receiving a certain favour in return. This is an open norm, as the exchange of "socially acceptable" gifts (including meals and hospitality) are allowed. The Dutch Criminal Code is enforced by the Public Prosecutor. If a case has been enforced under the advertising rules by the Healthcare Inspectorate (as unallowable hospitality) it cannot be investigated by the Public Prosecutor, however, if a criminal case is initiated first by the Public Prosecutor, an administrative fine may still be imposed. Assessment by the self-regulatory bodies does not necessarily preclude further investigation, either by the Healthcare Inspectorate or the Public Prosecutor.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The offering of hospitality is governed by the Dutch Medicines Act and CGR Code. It may only be offered to prescribing healthcare professionals and, in the context of scientific meetings, to nurses who may administer medicines.

If the hospitality is offered to a Dutch healthcare provider in relation to an event abroad, it should meet the Dutch standards. The event should also be compliant with the country where the hospitality takes place, as local law will govern the event. So it should probably be approved according to both standards.

Specific thresholds apply to hospitality offered for attending scientific meetings (see question 5.2 below). For meals offered in the Netherlands – i.e. in the context of a scientific meeting or a consultancy agreement, not upon a mere dinner invitation – €75 including drinks (including VAT) is still considered reasonable.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Yes, for travel expenses, accommodation and enrolment fees. The costs related to time, recreation, leisure, etc., may not be paid for. The allowed costs amount to (in brief) €500 per event with a maximum of €1,500 per year, or 50% of the actual costs spent.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

A company may be held responsible for the contents of scientific meetings, depending, *inter alia*, on its influence on the programme, which seems likely if it is the organiser but less likely if it is a mere financial sponsor. The financial sponsor has to ensure, based on a detailed financial budget, that the expenditure of its contribution stays within the acceptable limits (see question 5.2 above).

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes, these services must be documented in a services provision agreement, also including the compensation paid. The fee must be reasonable. Applicable maximum rates vary from €75 to €200 per hour. Meals and drinks reimbursed in the context of the performance of service agreements may not cost more than €75 including VAT.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes, provided that the services provision agreement, including the services and consideration, is documented, unless the services consist of filling out simple once-only questionnaires or surveys.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes, this may be possible on the basis of a consultancy agreement, provided that such research should be sufficiently relevant for the healthcare provider's practice.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, an advertisement must, *inter alia*, contain the name, the information necessary for the correct use of the product and an explicit request to read the instructions on either the package leaflet or outer packaging carefully.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

No, this is prohibited.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

The relevant case law suggests that disease awareness campaigns are only permitted if information related to public health or human diseases is being provided and no reference of promotional nature is made, either directly or indirectly, to specific medicinal products and/or specific pharmaceutical companies.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Advertisements for prescription-only medicines to the general public is prohibited (see question 6.2 above). Whether a press release is considered to contain information or is promotional by its nature, depends on its content and presentation, and is assessed based on the individual press release. Reference to a prescription-only medicine in a press release may be possible provided that the mentioning is relevant and that no claims are made. References to unauthorised medicines or indications may qualify as a forbidden promotion to the general public.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

There are no such specific restrictions. As these publications are directed at the general public, the information may not contain promotional claims.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Donations to patient support groups are a form of sponsoring, subject to the CGR Code. An agreement needs to be in place, and no influencing, advertising or exclusivity is allowed.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Yes, this is possible. Items may, for example, be provided in the context of patient support programmes, provided that they will only be provided after a certain medicine has been prescribed, i.e. they may not be used as a promotional tool. Also, the items should be of direct use to the patient in support of the use of medication.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

No, there is no national statutory or other obligation to disclose details of ongoing or completed clinical trials, although, on the other hand, pharmaceutical companies involved in clinical research are not allowed to demand the non-publication of any relevant medical findings.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

No, there is no such statutory obligation in the Netherlands – it is part of the CGR Code.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Yes, under the CGR Code. This affects Dutch holders of a manufacturing or wholesale licence, healthcare professionals based in the Netherlands and Dutch patient organisations, but also foreign companies that transfer value to Dutch healthcare professionals. All transfers of value of over €500, need to be reported on a yearly basis (by June), in the Central Transparency Register.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

This situation should not occur, as a written agreement with the healthcare professional should be in place, with an explicit consent to the disclosure.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

The CGR Code also applies to information or advertising on the internet. Often, claims on the internet form part of the complaints filed with the CGR.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

There are no specific requirements, but some technical restrictions need to be in place preventing the general public from accessing webpages intended for healthcare professionals, e.g. typing in the licence number of a prescription medicine.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

When linking to a website of a third party, the company will, in principle, become liable for the content of the third party's website.

There are no requirements tailored to the situation of reverse linking of independent websites to a company's website. A company will in general not be liable for the placing of links of which it is not aware and that it does not control.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

A company may provide very limited (technical) information about its medicinal products (e.g. the name of the products of the company and a link to an SmPC or patient leaflet). It may include an e-mail address for the public to ask the company questions.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The CGR Code refers to the use of social media. It should always be clear who the sender of a certain message is and to whom the message is addressed. Pre-registration of users may be required to avoid advertising to the general public.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

In July 2018, a new version of the CGR Code was adopted. The most significant change is a new paragraph covering "other financial relationships" that fall outside the scope of hospitality. This includes requirements for relations with members of the general public that are directly or indirectly involved in the prescription of medicines, such as nurses (the purpose of which may not be the promotion of prescription of medicines, which is, *inter alia*, achieved by demanding a reasonable fee), sponsoring of projects (of which the requirements materially have remained the same), and scientific awards (that should, *inter alia*, have an independent jury).

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

CGR has announced last year that a working group will render advice on how the CGR Code could be simplified. At the time of this publication, the advice was not yet known but is expected in the course of this year.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

No, there are no such trends *vis-à-vis* last year.

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Anke Heezius advises and represents many pharmaceutical, life sciences and food supplement companies in (veterinary) pharmaceutical regulatory law and litigation, *inter alia*, pharmaceutical advertising. She has extensive experience in helping companies comply with ever-changing rules and regulations on pharmaceutical advertising and interactions with healthcare providers. She has presented many cases in court and before self regulatory bodies, such as CGR.

Her in-depth understanding of the business activities of pharmaceutical companies enables her to put specific legal questions into a broader context. Clients include Dutch and foreign pharmaceutical and biotechnology companies and hospitals.

Anke obtained a Master's Degree in Chemical Engineering in 1994 and a Master's in Law in 2001. She has been practising law since 2001 and is registered as a lawyer at the Amsterdam Bar.

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# Norway

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Advertising of medicinal products is governed in Chapter 13 of the Regulation on Medicinal Products No. 1839 of 18 December 2009 (the "Regulation"), which has been issued pursuant to the Act on Medicinal Products, etc. No. 132 of 4 December 1992. These rules apply to any medicinal products marketed in Norway and is enforced by the Norwegian Medicines Agency ("NoMA").

In addition, the Norwegian Association of Pharmaceutical Manufacturers ("LMI") has adopted two sets of more detailed and specific industry rules governing the advertising of medicinal products – medicines for human and veterinary use, respectively. In the following, we refer to the rules that apply to medicines for human use only (the "LMI Industry Rules"). The LMI Industry Rules apply in addition to the advertising rules in the Regulation. Formally, they apply only to LMI member firms, EFPIA member firms and others who may have agreed to adhere to the LMI Industry Rules (hereafter collectively referred to as "member firms"). In practice, they are considered the general industry standard. The LMI Industry Rules were last updated in April 2019 and are enforced by a self-regulatory body, i.e. the Council for Information on Medicinal Products ("the Council"), which was established by LMI and the Norwegian Medical Association in 1975.

### 1.2 How is "advertising" defined?

Advertising is defined the same in Section 13-2 of the Regulation and Section 1.6 of the LMI Industry Rules as any form of written or oral mention, picture or free distribution of medicinal products and herbal medicines that is designed to promote the sale or use of the product.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Pursuant to Section 13-9 of the Regulation, firms must ensure that all sales representatives receive adequate training to be able to convey scientific information in a precise and comprehensive manner. Section 13-11 of the Regulation requires that marketing authorisation holders establish a professional information service and appoint a designated person who has the overall responsibility for the firm's information material. Section 13-11 sets out a number of specific tasks for the designated person to fulfil, including the following:

- submit copies of all written advertising materials to the NoMA or the Council;
- ensure that all firm's advertising materials comply with applicable laws and regulations; and
- ensure that sales representatives receive sufficient training and fulfil their obligations.

In addition, Section 29.1 of the LMI Industry Rules requires that the designated responsible person normally should be a doctor or a pharmacist, and that the name, formal qualifications and position of the person are reported to the secretariat of the Council. The designee shall also approve all advertising materials prior to publication. Section 29.6 of the LMI Industry Rules requires that member firms normally submit copies of all advertising materials, regardless of format, to the Council's secretariat in advance. NoMA has extended this requirement to apply to all marketing authorisation holders, thereby leaving certain supervisory authorities with the Council.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Pursuant to Section 29.1 of the LMI Rules, member firms are obliged to implement SOPs for the approval of advertising materials and of other activities. The general requirement is that SOPs shall aim to ensure compliance with the LMI Rules and applicable laws and regulations, without specification of which exact aspects should be covered.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No prior approval requirements apply, except for what follows from question 1.3 above.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Yes. Pursuant to Section 13-10 of the Regulation, NoMA may ban an advertisement and may also require issuance of a corrective statement in case of a breach of the Regulation. If there are repeated breaches, NoMA may ban all advertising for the medicinal product in question, either temporarily or permanently. Bans are subject to a right to appeal to the Ministry of Health and Care Services pursuant to ordinary administrative procedures, or to the courts.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Breach of the Regulation may result in criminal fines or imprisonment for up to three months. The Council may issue fines of up to NOK 300,000 for a breach of the LMI Industry Rules.

We are not aware of any cases in which firm representatives have been imprisoned for breach of the Regulation's advertising rules. In practice, fines issued by the Council are the most relevant sanction, in addition to advertisement bans issued by NoMA. Both are used frequently, and both types of cases may be initiated by NoMA and the Council based on complaints from competitors. Competitors may in principle also initiate legal proceedings before the courts if the claimant can demonstrate a genuine need to protect its interests, for example, the claimant or its products are affected by the breach. That being said, we are not aware of any past or pending cases to this effect.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The powers of NoMA co-exist with the powers of the Council. Although there is no formal division of power between the two, NoMA in practice normally investigates and handles cases in which issuing an advertisement ban is relevant, whereas cases in which fines are relevant are entrusted to the Council. If the Council is already assessing a case, NoMA will in practice often refrain from opening a parallel case, and *vice versa*.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Unfair competition between traders (typically) competitors is regulated by provisions in the Norwegian Marketing. A self-regulatory bode consisting of, *inter alia*, the Confederation of Norwegian Enterprises (NHO) and the Enterprise Federation of Norway (Virke) handles complaints filed by traders against other traders for violation of the Norwegian Marketing Act. It is also possible to initiate legal proceedings on the basis of unfair competition. Separate provisions apply for unfair competition towards consumers.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Pursuant to the Regulation (Section 13-3) and the LMI Industry Rules (Section 4.1), advertising is prohibited for any medicinal product as long as it is not approved and authorised for marketing. Pursuant to the LMI Industry Rules, the price for the medicinal product also needs to be pre-approved prior to any advertising taking place. Furthermore, it is a requirement under both sets of rules that the advertising complies with the content of the applicable SmPC.

In practice, this implies that providing information to healthcare professionals about unauthorised products is limited to providing professional and scientific information, for example, about on-going research projects and pipeline products, and the information must be non-promotional. Whether or not the latter is the case will depend on the content of the information, the context in which it is presented, and to whom it is presented to. For example, scientific meetings and meetings in the context of advisory boards may – depending on the circumstances – be relevant arenas for providing strictly scientific information. Formally, the assessment is the same whether the firm sponsors the event or not, but in practice, the risk of information being unlawful is probably higher if the firm has sponsored the event.

Off-label information is explicitly prohibited pursuant to the LMI Industry Rules (Section 4.1), so the situation is therefore the same.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Sharing information about unauthorised medicines is not permissible beyond what may be derived from question 2.1 above. This implies specifically that such information should be kept strictly non-promotional, professional and scientific if it is going to be published, e.g. in a scientific journal. Off-label information may not be shared in any circumstance.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

As a starting point, firms may communicate with the media through press releases. Due to the wide definition of "advertising", a press

release may nonetheless be considered an advertisement if the content is considered promotional. Therefore, issuing press releases are not a way to communicate information about unauthorised products or off-label information which would otherwise be unlawful.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

As a general rule, information about products in the pipeline should not be sent to healthcare professionals unsolicited. However, such information may – depending on the prevailing circumstances – be acceptable if sent in direct response to an unsolicited request from healthcare professionals. In this context, "unsolicited" means that the firm has neither taken the initiative to, nor encouraged the question from the healthcare professional.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

This decision has not led to any amendments to legislation or LMI Industry Rules.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Pursuant to the LMI Industry Rules, it is normally acceptable to send a booking letter/meeting invitation in which the recipient is asked to reserve time for receiving information about a "novelty" assumed to be of interest to him/her. There must be no mention of the launch of a new product, no indication(s) or provision of any kind of product information, and no hints that give associations to specific medicinal products. Such letters must be signed by the member firm as such and not by employees who work specifically within certain therapy areas.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Although market research exercises are not generally prohibited, they are also not explicitly exempt from neither the Regulation nor the LMI Industry Rules, so if they are promotional in nature, they could be considered advertising. The LMI Industry Rules, *inter alia*, specifies that market research exercises neither may be hidden advertising (Section 6.1) nor should aim at influencing respondents, conveying promotional messages or promote promotional relations (Chapter 26).

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Pursuant to the Regulation (Section 13-7), the following information is mandatory in advertisements directed at healthcare professionals:

- name, dosage forms and strength;
- all active substances, which shall be presented in clear fonts and clearly visible;
- name and contact information to the marketing authorisation holder and possibly the manufacturer;
- approved indication(s);
- contraindications;
- adverse effects, precautionary measures and interactions;
- dosage;
- package size;
- prescription class, prescription rules and rules on dispensing from pharmacies; and
- approved sales price per specified date and provisions for reimbursement rules.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Rather than defining explicit restrictions on the information that may not appear in an advertisement, the Regulation (Section 13-3) and the LMI Industry Rules (Chapter 8) define a number of positive and cumulative criteria an advertisement must meet in order to be lawful. Therefore, an advertisement must live up to the following criteria:

- be sober-minded, factually-based and promote rational use in accordance with applicable prescription rules;
- not provide a misleading or exaggerated view of the properties or the medical values of a medicinal product;
- not lead to use of the medicinal product that is not medically justified;
- be dated and in accordance with the SmPC;
- be accurate, balanced, truthful, objective and complete, so as to enable recipients to determine the medical value of the medicinal product for themselves; and
- be based on the latest possible evaluation of scientific material and clearly reflect this material.

Pursuant to the LMI Industry Rules, advertising that distorts, unduly emphasises or omits information or in any way is misleading, is explicitly prohibited. Claiming that a medicinal product does not have any adverse effects or that it does not involve risk of addiction is also prohibited.

An advertisement may refer to studies not mentioned in the SmPC, provided that the primary results/the conclusion conforms with the SmPC. This includes confirming or specifying information in the SmPC and not distorting or making such information complicated. In addition, studies not mentioned in the SmPC must meet the general requirements in the Regulation (Section 13-7) and the LMI Industry Rules (Section 8.9) in relation to use of references, including that they, *inter alia*, must be of scientific quality and available to the recipient.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Contrary to what applies in respect of advertisements to the general public, there are no such explicit restrictions for advertisements to healthcare professionals. However, endorsements by healthcare professionals are likely to pose a risk of compromising the general requirements to the effect that advertisements must be sober-minded and factually-based.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

No, it is not a requirement to obtain data from "head to head" clinical trials before any comparative claims are made.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Whereas comparative advertisements obviously must comply with all general requirements under the Regulation and the LMI Industry Rules, the latter sets out a number of specific requirements for comparative advertisements, including that they must be based on comparable and relevant product characteristics and that all products are presented in a balanced, just and objective manner.

In addition, the general rules of the Marketing Control Act will apply, including the prohibition against actions violating good business practice between businesses and the prohibition against misleading advertising (Section 26).

Further, the Regulation on Comparative Advertisement issued pursuant to the Marketing Control Act applies and defines a set of criteria that must be fulfilled in order for such advertisement to be lawful. These criteria largely correspond to the applicable requirements under the Regulation and the LMI Industry Rules.

Pursuant to the Regulation on Comparative Advertisement, it should be possible to use another company's brand name as part of the comparison, as long as this is done in a manner that is not discrediting or derogatory.

Given the prohibition against advertisements on products without marketing authorisation, it is highly unlikely that comparison with a competing product without marketing authorisation will be lawful.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

This is not explicitly regulated in the Regulation or the LMI Industry Rules. However, general rules will apply, i.e. if such distribution, due to its context or the context in which it is distributed, is considered promotional, the requirements pertaining to the advertisement must be met.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Yes, if drafted in accordance with what is set out in question 2.6 above.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

This is not explicitly regulated in the Regulation or in the LMI Industry Rules, and we are unaware of any cases in which this issue has been raised. However, provided that combination use is a prerequisite for Product A pursuant to its SmPC, and given the general requirement that advertising must conform with the approved SmPC, this suggests to us that the MA holder of Product A may promote the combination use, whereas the MA holder for Product B may not rely on the SmPC for Product A to promote combination use.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Pursuant to the Regulation (Section 13-8), samples may be provided to doctors, dentists, veterinaries and fish health biologists on the following conditions:

- Prescription medicines may only be provided to relevant healthcare professionals as samples if they are entitled to prescribe the medicine in question.
- Provision of samples may only take place following a written and signed request from the healthcare professional in question.
- Each healthcare professional may only be provided one sample of the medicine per year. If the medicine comes in multiple forms or strengths, a sample of each form and strength may be provided, corresponding to the smallest package on the market.
- Samples must be marked "Free pharmaceutical sample – not for sale".
- Herbal medicines must be marked "Herbal medicine".
- A complete copy of the SmPC must follow the sample.
- Providing samples of non-authorised medicinal products is prohibited.
- Providing samples of medicinal products classified in prescription class A and medicinal products containing substances classified pursuant to international conventions on psychotropic or narcotic substances, is prohibited.

- Each firm must keep records of all pharmaceutical samples it has provided. These must be retained for two years and be available to relevant authorities upon request.

These provisions are repeated and substantiated in the LMI Industry Rules (Chapter 24), which also specify that the purpose of samples is to let healthcare professionals familiarise themselves with the product, and that providing samples for more than two years after the introduction of a new product (i.e. new MA, strength or formulation in relation to approval of a new indication for an existing product), is prohibited. The LMI Industry Rules also expressly prohibit the use of samples with the intention to exercise an undue influence to recommend, prescribe, purchase, give, sell or administer a medicinal product.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

In practice, it is not. Pursuant to Section 9 of the Healthcare Personnel Act, healthcare professionals are prohibited from receiving – for themselves or others – any gift, commission, service or other performance that is capable of unduly affecting professional decisions, such as prescription decisions. Even if these rules only apply directly to healthcare professionals, and even if it is – in principle – lawful to receive minor gifts of insignificant value and that are incapable of exercising undue influence, the scope has been further narrowed in the LMI Industry Rules (Chapter 13). This provision contains a general and all-inclusive ban on all forms of gifts, such as pens, post-its and other inexpensive meeting supplies. In addition, general anti-corruption provisions in the Norwegian Penal Code may apply. Reference is made to the comments in question 4.9 below.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Whereas the Regulation does not contain express provisions to this effect, the LMI Industry Rules (Chapter 19) indirectly allow for aid in the form of objects of monetary value or financial contributions to healthcare organisations. Aid must be given for a specific purpose and may only be given to contribute to medical research or improved patient treatment. It may only be given following a written application from the healthcare organisation, describing the purpose, intended use of the aid and the budget. The aid must be specified in a written agreement between the firm and the healthcare organisation.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The Regulation has no specifics on this issue, but it is included in the LMI Industry Rules (Chapter 14). Whereas the provision of information or educational material – or medical aid to healthcare professionals or patients – may be permissible under certain circumstances, providing any such material to unduly influence decisions to prescribe (or recommend, purchase, give, sell or administer) a medicinal product, is explicitly prohibited; *cf*. Section 14.7 of the LMI Industry Rules. Any attempt to influence prescription patterns is therefore prohibited.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Neither the Regulation nor the LMI Industry Rules prevent volume-related discounts, but Section 6 of the Medicinal Products Act prohibits discounts that are not determined at the time of the sale of a medicinal product, which may complicate the contemplated use of rebates. It should also be taken into account that the sale of medicinal products to public hospitals normally is subject to regulated procedures, e.g. public procurement procedures, and therefore will have to be offered in this context. For the sake of good order, we wish to mention that rebates, depending on the circumstances, may have competition law implications.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Linking an offer for additional services or equipment to an obligation to purchase medicinal products risks being seen as a way to exercise undue influence on decision-making, e.g. on the institution's procurement decisions, and is thus in conflict with the requirement under Section 14.7 of the LMI Industry Rules; see question 4.4 above. Such linking of services and products could also have competition law implications.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Neither the Regulation nor the LMI Industry Rules explicitly prohibit the use of refund schemes. In light of the generally very restrictive approach to the advertising of medicinal products in Norway, we nevertheless find it likely that such a scheme would be considered contrary to the advertising rules, for example from the point of view that it does not promote rational prescribing.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Neither the Regulation nor the LMI Industry Rules prohibit sponsorship of continuing medical education, but this may be prohibited by way of bilateral agreements between the LMI and the relevant healthcare professionals' organisations or even with institutions. For example, the LMI and the Norwegian Medical Association have entered into a bilateral agreement that effectively excludes all sponsorship of mandatory continuing medical education for doctors.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Section 387 of the Norwegian Penal Code provides that any person who "*for himself/herself or others demands, receives or accepts an offer of an improper advantage in connection with the conduct of a position, an office or performance of an assignment*", may be indicted for corruption, with fines or imprisonment for up to three years. This is enforced by the public prosecution authorities. In principle, this provision is also applicable to interactions between the pharmaceutical industry and healthcare professionals. However, it is reserved for very grave circumstances, and we are not aware of any cases in Norway involving the pharmaceutical industry and healthcare professionals.

The prohibition on healthcare professionals against receiving gifts pursuant to the Health Personnel Act is enforced by the Norwegian Board of Health Supervision, which may act against healthcare professionals with administrative or even criminal sanctions, i.e. fines or imprisonment for up to three months.

In addition, the Council will enforce any violations of the prohibition of gifts through the LMI Industry Rules, where member firms risk being fined.

In theory, the public prosecution authorities and the Council may investigate the same facts under the Criminal Code and the LMI Industry Rules, respectively. However, such a scenario is highly unlikely, due to the fact that the threshold for violating the Penal Code is much higher that the threshold for violating the LMI Industry Rules.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

It follows from Section 9 of the Healthcare Personnel Act that healthcare professionals may not accept gifts, commission or other benefits that may unduly affect their provision of services. The regulation mentions covering expenses related to seminars and conferences as an example of a "gift". Therefore, healthcare professionals are not permitted to accept hospitality that is intended to influence them in an unduly manner.

The LMI Industry Rules contain more specific rules. According to the code, hospitality shall be limited to travel, meals and overnight accommodation, as well as necessary attendance fees.

The rules apply regardless of whether the hospitality offered to healthcare professionals takes place in another country. The member firms have a duty to make sure they comply with Norwegian rules.

The LMI Industry Rules state that funding participation, travel or stay for healthcare professionals for events abroad arranged by third parties, is prohibited. This typically applies to conferences. However, the prohibition does not prevent a member firm from inviting healthcare professionals to meetings during international conferences. All types of hospitality provided to healthcare professionals must be reasonable and necessary in relation to the academic programme.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The same rules referenced under question 5.1 apply to healthcare professionals' attendance at scientific meetings.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

There are no explicit rules on responsibility for pharmaceutical companies.

With regard to hospitality, etc., Section 9 of the Health Personnel Act applies to healthcare professionals, while the sections on corruption in the Norwegian Penal Code apply to both the company and the healthcare professional.

With regard to content, a pharmaceutical company may be responsible for the content of the lecturer's material if it is considered marketing.

The Council has the power to issue fines for LMI members in the event of a breach of the LMI Industry Rules.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Using healthcare professionals as consultants and advisors for assignments such as lectures, participation in clinical and other scientific studies, in-house personnel training, participation on advisory boards, etc., is permitted.

Healthcare professionals working for a public health company have a duty to inform the employer of such assignments, as well as the nature of the assignment and the agreed remuneration.

The remuneration shall be reasonable in relation to the service provided.

The LMI Industry Rules contain detailed provisions relating to the agreement and the information to be provided.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes, see question 5.4.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes, this is possible; see question 5.4.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

According to Section 13-5 of the Regulation, advertising non-prescription medicines to the general public is permitted within certain limits. For example, advertising for medicines should be neutral and objective. The advertising must not present a misleading or exaggerated picture of a product's properties and medical value.

In advertising to the general public, serious diseases cannot be mentioned.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

According to Sections 13-5 and 13-7 of the Regulation, advertising prescription-only medicines to the general public is prohibited. There is a prohibition on hidden advertising.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are permitted if the information is not connected to specific medicines, *cf.* Section 13-1 of the Regulation. The information in such campaigns shall be precise, correct, easy to understand and adapted to the general public. All printed materials must be dated and medically up-to-date. Also, the campaign must describe all main characteristics of a given disease and not selected aspects.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Press releases may be used to communicate with the press concerning prescription-only medicines to non-scientific journals. However, particular care must be taken to avoid the risk of the press release being considered advertising. The mention of product names or specific active substances are factors indicating that the press release is marketing.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Products and research initiatives may be described as background information in corporate brochures/annual reports. However, any mention of product names or specific active ingredients must be kept to a minimum to avoid having the material be considered marketing.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

A manufacturer may work with patient and user organisations to support their work, such as providing information to patients and their relatives and sharing the manufacturer's competence. However, ordinary rules apply, and it is important to avoid marketing for prescription-only medicines, which must only be directed at healthcare professionals.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

It is not permitted to advertise for prescription-only medicines. This includes using gifts, prizes or any other form of reward as part of marketing efforts. The distribution of free drug samples to the general public is not permitted.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

There is no obligation to disclose details of clinical trials. However, all research projects in Norway are subject to pre-approval by the Regional Ethics Committee, *cf.* Section 9 of the Act on Health Research. Limited information on the study, e.g., the project description, will be disclosed in a public portal.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

The legislation does not require making such information publicly available, but the LMI Industry Rules does. Such transfers must be disclosed on the company website.

The LMI Industry Rules apply to LMI members, but non-members will usually report.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The LMI Industry Rules state in Chapter 26 that the LMI member firms must publish direct and indirect transfers of value to healthcare professionals and health organisations. Reference is made to the EFPIA Disclosure Code. The rules apply to LMI members and should be disclosed either in individual or aggregated form.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

For disclosure of transfers related to healthcare professionals, the member firm must ensure that there is a basis for the processing in accordance with the Personal Data Act, which implements GDPR. If there is no basis for processing, the value transfer shall be reported in aggregated form, *cf*. LMI Industry Rules Section 26.5.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

There are no statutory rules directed specifically to Internet advertising on pharmaceutical products, but the rules apply regardless of format.

The fact that the rules apply regardless of format is especially stated in the LMI code, which also includes more detailed guidelines.

The opening page of the website that is addressed to the public and healthcare professionals alike should be suitable for both target groups and may not include advertisements for prescription medicines.

Advertising on the Internet is rather successfully controlled. LMI members must submit an overview of their own websites, as well as websites that they contribute to.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Again, there are no specific statutory rules in the Act on Medicinal Products and regulations.

The LMI Industry Rules state that whoever owns or contributes to the site and whatever target audience (public or healthcare professional) the site is targeting, should be clear to the user of a website. If the site only addresses healthcare professionals, this must be clearly stated in a disclaimer or similar before access to the opening page is granted.

There must be a clear distinction between pages intended for health professionals and the general public, respectively. When navigating to the site, it must be easy for the user to see that a page applies only health professionals before viewing such a page.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

The Regulation does not contain specific rules regarding such issues.

Banners on websites have limited display areas for advertising. The LMI Industry Rules state that such advertising shall only contain the name of the medicinal product and the generic name of the active substance and the name of the marketers, *cf*. Section 8.3 of the LMI Industry Rules.

A company may be liable for content to other sites it has links to, but this will require an active involvement of some kind. Normally, a disclaimer stating that the link directs the user to a third-party site will be sufficient, but circumvention of the rules will not be tolerated.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Ordinary rules on advertising apply.

Advertising for non-prescription drugs that are published on the Internet and which are aimed at the Norwegian public must comply with all relevant provisions in the Marketing Control Act.

Compulsory information for prescription drugs may be included in the link, provided that the link is clear and easy to see, and that it is a direct link ("one-click").

The company should list the company name and organisation number on the webpage, and should also provide contact details.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no statutory rules directed specifically to social media, but the ordinary rules apply. The LMI Industry Rules also apply, including the chapter on the Internet, television and other media. This means that any information published on social media shall comply with all relevant provisions of the LMI Industry Rules. However, with regard to social media, it is important to be aware that there is a prohibition against hidden advertising.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

There have been no significant developments in relation to the rules relating to pharmaceutical advertising in Norway in the last year.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

There has been a hearing on a proposal to amend the Regulation. The background for the proposed amendments is in part a need to harmonise this chapter on advertising with EEA law, in particular Directive 2001/83/ EC ("the Directive"). One of the issues is the proposal that The Norwegian Medicines Agency shall monitor and control the advertising of medicines. It will be interesting to see whether the industry will be permitted to continue with self-control and self-monitoring to the same extent as today.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There are no significant trends in pharmaceutical advertising in Norway that have become apparent over the last year.



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Kirti is recognised by *Who's Who Legal* as an expert in life sciences regulatory law with nearly 20 years of experience that encompasses the entire spectre of regulatory legal framework for the healthcare sector. She renders advice regarding: authorisations, approvals, registrations, CE marking; pharmaceutical trade; pricing and reimbursement; distribution/market access/marketing; interaction with HCPs; administrative sanctions against HCPs; product liability for pharmaceuticals and medical devices; and regulatory due diligence.

Kirti has extensive experience handling procurement in the healthcare sector and assists with practical and legal challenges that emerge in these processes. She assists suppliers with quality control of bids before submission and in safeguarding their interests during the entire procurement process, complaints and court processes.

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Rune has 17 years of experience, working mainly with IP, life sciences and IT/technology law. He has in-depth knowledge of business law, with a focus on intellectual property, marketing, contracting, competition, public procurements and protection of privacy and employment.

A significant part of Rune's work relates to international clients. He is an experienced litigator in complicated patent, trademark and technology cases. Rune also has broad experience in developing and executing strategies on anti-counterfeiting.

He advises on compliance with medical law and advertising regulations for a broad range of products, including issues related to packaging, labelling and distribution. Rune is experienced in advising on misleading and unfair commercial practices. His practice also includes advice on compliance with codes of conduct, as well as with bringing complaints and defending cases before regulators, appeals of regulators decisions and in court processes. Rune also has extensive experience within public procurement in the health sector.

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# Poland

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products is regulated in the Act of 6 September 2001, the Pharmaceutical Law ("Pharmaceutical Law"). The matter is also governed by the Regulation of the Minister of Health of 21 November 2008 on Advertising of Pharmaceutical Products and the Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices of 12 May 2011 ("Act on Reimbursement").

Additional rules and guidelines are provided by codes of conduct and ethics:

- INFARMA (Polish union of innovative pharmaceutical companies) Code of Good Practices in Pharmaceutical Industry (implementing in Poland the EFPIA Code on The Promotion of Prescription-Only Medicines to, and interactions with, Healthcare Professionals).
- INFARMA Disclosure Code (implementing in Poland the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations).
- IFPMA Code of Practice.
- POLFARMED Code of the Pharmaceutical Marketing Ethics of Prescription-Only Medicines.
- Physicians' Code of Ethics.
- Pharmacists' Code of Ethics.

### 1.2 How is "advertising" defined?

The advertising of a medicinal product is defined in the Pharmaceutical Law as any activity consisting of providing information or encouraging the use of a product with the purpose of increasing the number of issued prescriptions or the supply, sale or consumption of medicinal products.

The following materials are not considered as advertising of medicinal products:

- information on (and attached to) packaging conforming with marketing authorisation;
- correspondence containing informative materials that are not of a promotional nature and are needed to address questions about a particular medicinal product (including materials referring to unauthorised products available on a named-patient basis);
- informative non-public announcements relating to packaging changes and adverse reaction warnings (which may not include references to product properties);
- trade catalogues or price lists containing no references to product properties or therapeutic indications; and
- information relating to human and animal health or diseases, provided that it includes no direct or indirect reference to medicinal products.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

No formal arrangements consisting of "sign off" or approval of promotional materials are imposed on companies. Marketing authorisation holders are, however, obligated to ensure that draft advertisements are stored for two years from the end of the calendar year in which the advertising was broadcast.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Companies are not required by law to implement SOPs nor to employ personnel with a specific role related to advertising. The companies, however, may employ as medical or commercial sales representatives, only persons having sufficient technical knowledge that allows them to present adequate and accurate information on the advertised medical products. Furthermore, under the Code of the Pharmaceutical Marketing Ethics of Prescription-Only Medicines, companies are required to implement internal organisational and procedural systems guaranteeing their full control over advertising and promotional activities and compliance with the Code.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The law does not provide for any official approvals of pharmaceutical advertising. There is also no possibility to request a prior approval by the regulatory authorities.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The Main Pharmaceutical Inspector is authorised to issue a decision prohibiting further publishing of the advertisement infringing the applicable provisions regulating the advertising of pharmaceutical products and removing its effects. The Main Pharmaceutical Inspector may order the company to publish such a decision in places where the advertisement was previously published or to publish a corrective statement. The decision may be appealed by way of a motion for re-examination (the case is then once again assessed by the Main Pharmaceutical Inspector), and may be later submitted for review by the administrative courts.

Advertising contrary to law may also, in certain circumstances, infringe the collective interests of consumers in the meaning of the Act of 16 February 2007 on Competition and Consumer Protection. In such case, the Chairman of the Office of Competition and Consumer Protection may issue a decision ordering the advertiser to cease infringement and also impose a fine reaching up to 10% of last year's revenue of the perpetrator. An addressee of such decision is entitled to appeal to the Court of Competition and Consumer Protection.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The Pharmaceutical Law specifies that in a case of non-compliance with the rules governing advertising, a company may be subject to a fine, which is imposed by the court in criminal proceedings. A decision imposing the obligation to cease advertising may be issued by the Main Pharmaceutical Inspector or the Chairman of the Office of Competition and Consumer Protection; the fines may also apply. The decisions imposing the obligation to cease advertising are quite common – the Main Pharmaceutical Inspector usually issues several such decisions per year.

Furthermore, competitors and consumers are also entitled to take direct action in relation to advertising infringements. Pursuant to the Act of 16 April 1993 on Combating Unfair Competition, an entrepreneur whose interest is threatened or infringed by the act of unfair competition (in this case, advertising contrary to law or good business practices) may demand that the competitor:

1. ceases the prohibited activity;
2. eliminates its effects;
3. publishes one or several corrective statements;
4. pays damages and accounts of profits; and
5. if the activity is deliberate – pays a specific amount to a social cause.

Claims listed in points 1–3 and 5 above may also be raised by a national or regional organisation protecting the interests of entrepreneurs.

Under the Act of 23 August 2007 on Counteracting Unfair Market Practices, a consumer whose interest is threatened or infringed by the release of an illegal advertisement is entitled to demand the advertiser take action as listed above. These claims might also be raised, *inter alia*, by a local consumer advocate and a national or regional organisation protecting the interests of the consumers.

The claims connected with the acts of unfair competition or unfair market practices are pursued in civil proceedings before general courts. Prior to filing a lawsuit, a claimant may file a motion for preliminary injunction to stop the infringing practice during the court proceedings.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The two mentioned processes are mostly independent. The authorities may investigate matters constituting a breach of law and a relevant code independently from self-regulatory bodies. It is worth noting that according to the Code of the Pharmaceutical Marketing Ethics of Prescription-Only Medicines mentioned in question 1.4 above, when a self-regulatory body issues a decision which is not observed by an entity in breach, the case may be referred to the Main Pharmaceutical Inspector.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Actions based on unfair competition law may be taken by the competitors of a given entity, while actions based on unfair market practices may be taken by consumers. Furthermore, a national or regional organisation protecting the interests of entrepreneurs (i.e. competitors of an entity being in breach), a local commissioner of the consumers and a national or regional organisation protecting the interests of consumers might also instigate proceedings. The claims available to these entities are listed in question 1.7 above.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

According to the general principles, trading in unauthorised medicinal products is prohibited. The Pharmaceutical Law expressly prohibits the advertising of medicinal products not authorised to the Polish market (both advertisements addressed to the general public and to professionals). It is, however, argued that the possibility of providing professionals with such information is desirable. Such data should be of a scientific and not of an advertising nature in order not to violate the provisions of the Pharmaceutical Law.

The advertising of medicinal products, irrespective of whether they are addressed to the general public or to healthcare professionals, cannot include information contrary to the SmPC. This means that commercial communications cannot use any claims or refer to any indications which are not based directly on the SmPC. From a practical point of view, determining the admissibility of given communication requires analysis of its form and the way it was presented. As a general rule, presenting any information on a meeting sponsored by the company is more likely to be considered as unlawful than presenting data on the independent event.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

According to the position of the Main Pharmaceutical Inspector, the information on off-label use may only be published in professional literature, not in any promotional materials. In the past, off-label information published on a pharmaceutical company's website was considered as unlawful even if the company claimed that it was merely information, not promotional materials, and despite the fact that the off-label use was indirectly "authorised" by the decision of the Minister of Health granting reimbursement for certain off-label indications.

It is also worth noting that the authority has stated that sending copies of the reimbursement decision for off-label indications would be, in its view, an action of a strictly informative character (which implies that such communication would be accepted by the Main Pharmaceutical Inspector).

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Issuing press releases about unauthorised medicines or off-label information in general media is not permitted, as such materials would most likely be considered as advertising. Publishing information about unauthorised medicines and/or off-label information in professional media would be acceptable as long as the information is purely scientific. Please also see question 2.2.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

There is no explicit regulation in Polish law that would allow information to be sent even when requested by the healthcare professionals. However, if such information is not of promotional nature, in particular, when it does not refer to the name of the product but is generic and is a response to a submitted question about the product, it should not be considered as an advertisement and would therefore be allowed. Therefore, any information should be sent to healthcare professionals only if requested and should not be of a promotional nature.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

In 2011, the Pharmaceutical Law was amended. By virtue of this amendment, trade catalogues and price lists containing exclusively basic information on a product (including non-approved products imported on a named-patient basis), such as name, dosage, form and price, are not considered advertising, provided that their contents do not include any claims as to the product's properties or its therapeutic indications.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Polish law does not provide for such an exception.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Physicians may not be engaged in actions aimed at the promotion of any medicinal product or its indications. They may only participate in a given research exercise provided that its nature is strictly scientific and not promotional.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Advertisements directed to healthcare professionals must include information consistent with the SmPC, as well as information on the approved dispending category and, in the case of products reimbursed from public funds, information concerning its official retail price and the maximum surcharge amount paid by the patient. The specific list of information which must be provided is extensive and is set forth in the Regulation of the Minister of Health of 21 November 2008.

The information should be reliable, up-to-date, verifiable and sufficiently complete so that the addressee can make his own judgment of the products' therapeutic value. The materials should also indicate the date they were prepared or last updated. Any quotations, tables and visuals from scientific papers must be truly and faithfully copied and the source of information disclosed.

Advertising directed to healthcare professionals must be distributed in a manner ensuring that it is not accessed by the general public. For instance, when presented on the Internet, the website should require recipients to log in and verify their professional status. The pharmaceutical company is responsible for securing the materials intended for healthcare professionals and may be liable for the unlawful advertising of medicinal products to the public.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

An advertisement may refer only to some of the therapeutic indications, but in such case all the remaining information in the advertisement must be related only to those chosen indications. The advertisement cannot include information inconsistent with the SmPC.

Advertising should not refer to studies which are contradictory to the contents of the SmPC or present information that does not appear in the SmPC. For instance, it is not possible to refer to studies showing possible off-label use of the product.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Such restrictions apply only with regard to advertising to the general public. Nevertheless, Polish physicians' self-governing bodies consider participation of physicians in the promotion of medicinal products as contrary to the professional code of conduct.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

There is no such specific requirement in Polish law.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Under Polish law, a comparative advertisement is governed by the rules of unfair competition and trademark protection and is generally permitted under Polish law only if it is not contrary to law or good practice.

Furthermore, with regard to the advertising of a medicinal product addressed to the general public, the Pharmaceutical Law forbids assuring that the effect of one medicinal product is superior or the same as another medicinal product. It must also be remembered that advertising of products which have not yet been authorised on the Polish market is forbidden – comparative advertising by referring to non-authorised products or indications could violate this rule.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Scientific papers and/or proceedings of congresses may be provided to healthcare professionals if they do not constitute endorsement to use/purchase/prescribe a given product, but only present scientific issues. In other matters, such materials will be classified as advertising.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

No express prohibition of publishing such information is contained in the applicable legal provisions. Such "teaser" advertisements would not fall within the definition of pharmaceutical advertising if they do not mention a specific product or encourage the consumer to buy such product.

It should also be noted that pursuant to the Pharmaceutical Law, it is also possible to present short advertisements serving merely as a reminder of a full advertisement of a medicinal product. Such advertisement, in addition to its market name and international non-proprietary name, may only contain a trademark with no references to therapeutic indications, pharmaceutical form, dose, advertising slogan or other advertising content. Furthermore, according to regulatory authorities, such "reminder advertisement" may only be used after a full advertisement was broadcast.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Based on the Pharmaceutical Law, commercial communications cannot use any claims or refer to any indications which are not based directly on the SmPC. Thus, it should be pointed out that advertising for a particular indication will be possible only if it is included in the SmPC. The MA for product A will be able to indicate in the SmPC that his medicinal product may be used with Product B in that indication, provided that the SmPC will be approved by competent authorities. If the SmPC has been accepted, such combination use may be promoted by the holder of the MA for Product A.

The holder of the MA for Product B must first vary the Product B's SmPC. Then, advertisement of such indication will be possible.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes, but the samples may only be provided to professionals entitled to write prescriptions. A given healthcare professional has to request a respective company to provide him/her with samples in writing. Moreover, the samples provided to professionals must be evidenced by the provider. A sample needs to constitute the smallest packaging of a product authorised on the market and should be marked with the sign "free sample – not for sale" (Pol. "*próbka bezpłatna – nie do sprzedaży*"). The sample must be accompanied with the SmPC. Moreover, one professional is entitled to obtain no more than four samples of one product per year. Samples of intoxicants and psychotropic products cannot be provided.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Medical practitioners may only receive gifts of a value not exceeding PLN 100 and which are related to their medical or

pharmaceutical practice. Those gifts cannot be marked with elements/trademarks of the advertising product but they must be clearly marked with a logo or trademark of the company. Donation of money is not allowed.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

It is usually argued that providing donations to institutions such as hospitals is allowed, although it may be questioned if the donation was clearly meant to influence the decision-making process of the institution or professionals in favour of the donor. Donations or gifts given to healthcare organisations are only allowed if:

a. they are explicitly intended to support healthcare or research;

b. they are documented and the documentation is kept by the donor; or

c. they are not incentives to recommend, prescribe, purchase, supply, sell or use specific medicinal products.

There are no specific monetary limits provided. Donations to individual healthcare professionals are prohibited. This does not apply to donations which are admissible by the provisions of the Pharmaceutical Law and the provisions of the INFARMA Code of Good Practices in Pharmaceutical Industry.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

As a general rule, Pharmaceutical Law forbids free donations to healthcare professionals (see question 4.2 above) in order not to allow them to be influenced by the drug manufacturers. Medicinal products prescribed by a physician need to be selected by him/her solely on the basis of objective assessment. Such assessment may be supported by educational materials furnished by a pharmaceutical company, but must primarily result from the doctor's freedom of conscience and current medical knowledge.

A professional cannot be remunerated for prescribing a given product. Under the Act on Reimbursement, no incentives or benefits of any kind (financial or personal) may be offered to healthcare professionals authorised to write prescriptions. Non-compliance with this restriction may result in fines of up to 5% of the turnover of the reimbursed products.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Such discounts can be considered as a material benefit connected with the purchase of the products that are not allowed under the Pharmaceutical Law. Furthermore, the Act on Reimbursement provides that a manufacturer of reimbursed medicinal products (or medical devices) cannot differentiate prices of such medicinal products in agreement with wholesalers, as the prices are fixed. For reimbursed products, all other forms of incentives are also prohibited, e.g. conditional sale, discount, donation and participation in loyalty programmes.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Additional services should be provided upon remuneration in order not to be considered as an unlawful material benefit connected with the purchase of products. In the case of reimbursed products, any volume-related additional services could also be regarded as prohibited incentive or benefit under the Act on Reimbursement.

It is important to remember that under the Act on Reimbursement, no incentives or benefits of any kind (financial or personal) may be offered to healthcare professionals authorised to write prescriptions. Non-compliance with this restriction may result in fines of up to 5% of the turnover of the reimbursed products. It is worth emphasising that under the Pharmaceutical Law, it is prohibited to direct these advertisements at persons authorised to write prescriptions and persons that distribute medicinal products advertising involving the gift, offer and promise of material benefits, presents and other inducements, prizes, trips and the organisation and financing of meetings to promote medicinal products during which hospitality exceeds the main purpose of the meeting. As we mentioned above, that provision does not apply to the giving or accepting of items valued at under PLN 100 and relevant to the practice of medicine or pharmacy, bearing a mark advertising a given firm or medicinal product.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Refund schemes cannot be addressed to the general public, since it would constitute forbidden advertising suggesting that taking the medicinal product guarantees the appropriate effect. Similarly, such schemes cannot be offered in respect of reimbursed products as it would constitute forbidden incentives. With respect to other products, general regulations regarding combating unfair competition shall apply.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Generally yes, pharmaceutical companies can sponsor the continuing of medical education, provided that sponsorship is not aimed at the promotion of a given company or a given product, in which case it will be regarded as advertising. It should be emphasised that no gifts or other benefits must be offered to participants or beneficiaries, since this would exceed the mere sponsoring of education and could be regarded as forbidden benefits. Furthermore, payment for a professional's expenses related to an educational meeting aimed at medical education will be classified as sponsoring. The extent of such payments may not exceed the level adequate to the main purpose of a given meeting.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

General anti-bribery rules applicable to interactions between pharmaceutical companies and healthcare organisations and individuals serving public functions are included in the Polish Criminal Code and Act on Central Anti-Corruption Bureau. Providing or accepting any financial benefit to a person performing a public function in order to influence the action of this person may be considered as unlawful and result in criminal liability. Anti-corruption investigations are conducted by public prosecutors or the Central Anti-Corruption Bureau, and are generally independent from the supervision of the pharmaceutical advertising performed by the Main Pharmaceutical Inspector. Therefore, public prosecutors may (and in practice they do) investigate matters even if they are already being assessed by other authorities or self-regulatory bodies.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

In principle, pharmaceutical companies may offer hospitality to healthcare professionals. However, such hospitality should not exceed the level adequate to the main purpose of a meeting or a trip and it may be offered only to healthcare professionals, not to their companions. The main purpose of a meeting needs to be related to medical or pharmaceutical practices and it is recommended that meetings are organised in locations that are adequate to their purpose.

The expenses should be generally limited to covering the costs, such as travel, accommodation or engagement in the meeting, as mentioned below in question 5.2. Under the Code of Good Practices in the Pharmaceutical Industry, the threshold for the value of meals is PLN 200 for meals offered in Poland and EUR 100 for meals offered abroad. There are no general requirements for approving the arrangements if hospitality is offered in another country.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

A professional might be entitled to remuneration for his/her contribution (as a speaker or moderator) to a scientific meeting, provided that such remuneration is adequate to the extent of his engagement in the meeting. Paying for mere participation in a meeting (costs of travel, accommodation and enrolment fees) is also possible, provided that the physician submits a report on the topics of the conference. However, an additional payment for such person's time might be classified as offering a material benefit.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

There are no specific rules regarding the extent of responsibility in such case. A pharmaceutical company may be held responsible for the events within its control, therefore it will be liable for the content of meetings organised or sponsored by the company. Where a meeting is organised by an independent third party without the company's involvement apart from providing sponsorship for a healthcare professional to attend, the company will not be responsible for its content.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Healthcare professionals may be employed as consultants or advisers on the provision of services which involve the need to pay remuneration and cover other costs related to the provision of services, e.g. travelling expenses or other reasonable expenses which need to be incurred for the performance of the agreement. In particular, such services may apply to the following: speeches or presiding over events; involvement in medical or scientific studies/research; clinical trials; training; participation in meetings of advisory bodies; or participation in market research.

The abovementioned cooperation shall satisfy all of the following conditions:

a. a written or documented contract is signed before providing the services, stipulating the nature of the services to be provided, as well as the grounds for making payment for the services;

b. there is a reasonable need for providing such services which has been clearly identified before ordering such services and before making arrangements with potential consultants;

c. the consultant selection criteria are directly related to the identified need, while the persons responsible for the selection have the knowledge required for assessing whether given healthcare professionals meet these criteria;

d. the number of service providers shall not exceed the reasonable number of persons required for the purpose of satisfying the identified need;

e. the signatory of the INFARMA Code of Good Practices in Pharmaceutical Industry shall keep the appropriate documentation and shall appropriately use the services provided by the consultants;

f. the employment of healthcare professionals for providing a given service shall not be an inducement to recommend, prescribe, purchase, procure, sell or use the medicinal products; and

g. the fee offered is appropriate to the market value of the services provided.

It is recommended that contracts with healthcare professionals incorporate appropriate provisions obligating them to include a declaration stating that he/she has entered into a contract with the pharmaceutical company in all his/her public appearances or written works with regard to matters constituting the subject matter of the contract.

Where pharmaceutical companies hire professionally active healthcare professionals as part-time employees, it is recommended that the contracts contain a clause obligating the hired person to provide information that he/she is employed by the given company in public appearances or written works regarding the subject matter of the employment. There should also be an obligation to inform other employers and other persons, to whom the employee represents the interests of his/her employer, of the contracted employment in question. Such an obligation exists regardless of the nature of the matters which constitute the subject matter of the employment, namely regardless of whether or not they are related to the advertising of the medicinal product. It is recommended that contracts concluded by and between pharmaceutical companies and healthcare professionals contain an obligation of the healthcare professional to obtain the consent of his/her employer or the entity to which it continuously provides services to taking up the cooperation specified in the contract, with particular account taken of the need to avoid conflicts of interest.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Healthcare professionals should not be engaged in any actions aimed at the promotion of a particular medicinal product. Any studies performed by physicians need to be of a strictly scientific nature. Physicians should also disclose their ties to a particular pharmaceutical company, including disclosures to the audience during lectures and to editors of publications.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Generally, no. The prohibition of taking part in activities aimed at the promotion of a medicinal product is interpreted broadly. Additionally, the Physicians' Code of Conduct forbids participation in any scientific research with the purpose of promoting products (see also question 5.4).

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes. Advertising should include the following information: the name of the product and the common name of the active substance; the dosage of the active substance; the pharmaceutical form; therapeutic indications and contraindications; and the identity of the marketing authorisation holder. A warning concerning the need to verify the content of the leaflet or to consult a doctor or a pharmacist must also be included.

Additional information which must be provided is listed in the Regulation of the Minister of Health of 21 November 2008.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

It is not possible to advertise prescription-only medicines to the general public.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Yes, the provision of general information is permitted provided that it does not comprise any elements aimed at endorsement to use/purchase particular medicinal products. The provision of information on vaccination campaigns is expressly allowed in the Pharmaceutical Law.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

If such press release contains an element of endorsement, it will be regarded as advertising. Since non-scientific journals are accessed by non-professionals, press releases concerning prescription-only medicinal products are generally prohibited. Similarly, press releases on yet unauthorised medicines or indications are generally prohibited, as Polish law bans the advertisement of unlicensed products.

In practice, when a pharmaceutical company aims to target professionals through advertisements (as in the case of advertising prescription-only medicines) it should undertake necessary measures to effectively restrict such content. It is not sufficient to merely include a warning that the material is only intended for professionals.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Products and research initiatives can be described in such brochures and reports provided that they are not used as a form of hidden advertising of medicinal products or classified as an endorsement to purchase or use the product. The materials should be marked as intended for investors, shareholders etc., and should not be made available more broadly than usual for similar corporate materials; in particular, purposefully made available to patients.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Meetings with, or the funding of patient organisations are allowed, provided that they comply with the general rules applicable to advertising to the public. Such measures cannot be used to promote prescription-only products. A product cannot be advertised by publicly known persons, doctors or pharmacists and may not refer to any recommendations made by those persons.

During meetings, a company cannot present information indicating that: (i) one may avoid consulting a doctor; (ii) a product might improve the condition of a healthy person; (iii) the condition of a person might deteriorate in the case he/she does not use an advertised product; (iv) a medicinal product constitutes food stuff, cosmetic product, etc.; (v) the effectiveness of a product results from its natural origin; and (vi) the positive effect of using a product is guaranteed. What is more, the provided information: may not specify improper effects of a product with regard to the human body; cannot lead to improper self-diagnosis; or cannot refer, in improper, alarming or misleading terms, to therapeutic indications.

Provided that the above general rules are observed, a company is entitled to organise meetings with a patient and to finance patient support groups. Additional requirements regarding transparency are introduced by the Code of Good Practices in Pharmaceutical Industry implementing the EFPIA HCP Code.

The provision of financial and non-financial support, directly or indirectly (e.g. through a third party) to a patient organisation requires the conclusion of a contract in writing. The contract shall stipulate:

a. the subject matter of the contract;
b. the date of conclusion of the contract;
c. the names of cooperating institutions and a third party, if applicable;
d. the purpose of the support;
e. the amount or value of the support;
f. the responsibilities of the parties;
g. the terms and conditions of the contract;
h. a description of the support to be provided;
i. the obligation of the patient organisation to observe the INFARMA Code of Good Practices in Pharmaceutical Industry when executing the contract; and
j. the obligation to provide evidence confirming that the support was used in accordance with the contract.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The Pharmaceutical Law does not allow for providing any material benefits connected with the purchase of medicinal products. In this respect, regulatory authorities have challenged the activities of providing patients with items of small value (e.g. socks, cosmetics products and cases for pills with no name stating the product inside it) while purchasing the medicinal products. Providing items that are not strictly related to the given medicinal product may be considered as unlawful.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Polish pharmaceutical regulatory bodies keep a Central Register of Clinical Trials. However, this data is not available to the public. No additional legal requirements to publicly disclose information on ongoing or completed clinical trials have been implemented. There is a self-regulatory initiative to publish the information on ongoing clinical trials conducted in Poland in the database kept by INFARMA.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no general obligation in the legislation to disclose transfers of value offered to the above entities imposed on the pharmaceutical companies. However, such information is in some cases made public by the beneficiaries due to the public functions they perform. For instance, national and regional healthcare consultants who are advisors to governmental and local bodies in matters of health policy, medical education, etc., have, from 2014, been obligated to disclose any ties with pharmaceutical companies and any benefits exceeding PLN 380.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

From 2016, INFARMA applies a Disclosure Code, which is binding only for its signatories. Under the Code, the signatories are obligated to document and disclose all the transfers of value offered to healthcare professionals or healthcare organisations in Europe. The data is made available on the website of each company within the last six months of the year.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

There are no regulations in Polish law that would require or allow a company to take any action if a healthcare professional refuses to agree to the disclosure. As publishing information without consent may violate the provision of processing the personal data, only cooperation with healthcare professionals who agree to disclosure is recommended.

According to INFARMA's practice, if the healthcare professional refuses to disclose the information on transfer, the data concerning cooperation with this healthcare professional should be presented together with other aggregated data.

## 8 The Internet

### 8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

No separate set of regulations apply to Internet advertising. According to Polish legal writings, an Internet advertisement should be assessed according to the provisions regulating radio, TV or press advertisements – depending on the content and method of advertising on the Internet. Apart from that, the general rules on advertising apply. Additionally, content of websites owned or sponsored by pharmaceutical companies is specifically regulated under the Code of Good Practices in Pharmaceutical Industry.

### 8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

According to the Main Pharmaceutical Inspector, websites should include adequate security measures to prevent the content directed to professionals from being accessed by the general public. Such measures may, for instance, include entering a log-in/name and password together with a verification whether the user is in fact a professional. Warnings included in the main site, or a pop-up asking whether the user is a professional, are not considered as sufficient. If an advertisement addressed to professionals may be easily accessed by the general public, it will be classified as advertising to the general public and will have to comply with applicable limitations.

### 8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

A mere publication of a link cannot be regarded as a breach of the law unless the pharmaceutical company is aware that the website presents unlawful advertising. A pharmaceutical company is responsible for its own websites, but not for independent websites linking to the official company's website.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Information published on a website must be of a neutral character (e.g. an image of product packaging with a name, basic information and characteristics of a given product). For prescription-only medicines, an image of the product's package, along with the full contents of a leaflet or the SmPC is allowed; however, every omission in the information which can be explained only by an advertising purpose (for instance, omitting the list of contraindications or possible adverse effects) is prohibited. Publication of advertisements addressed to the general public is also permitted, as long as such advertisements comply with the rules and restrictions applicable to the advertising of medicinal products.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There are no specific rules related to the use of social media for advertising in Poland. General rules for public advertising apply.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

No significant amendments to statutory provisions related to pharmaceutical advertising were brought in 2018.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No definite changes in the field of pharmaceutical advertising are expected in the next year.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

No general practice and enforcement trends or enforcement trend became apparent over the last year.

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SOŁTYSIŃSKI KAWECKI SZLĘZAK

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# Portugal

Cuatrecasas

Joana Silveira Botelho

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products is governed by the following laws and regulations:

(i) Decree-Law 176/2006, of August 30 (Medicinal Products Act).

(ii) Decree-Law 330/90, of October 23 (Advertising Code).

(iii) Decree-Law 5/2017, of January 6, which approved the general principles on the advertising of medicinal products and medical devices and the rules on the scientific sessions to be undertaken at the hospitals of the National Health Service.

(iv) Regulation 044/CD/2008 of Infarmed (Portuguese Medicinal Products Agency).

(v) Ministerial Order 5657/2017, of June 28 (clarification on the obligations established under Decree-Law 5/2017).

(vi) APIFARMA – Code of Conduct governing the Relations Between Pharmaceutical Industry and Patients' Organizations.

(vii) APIFARMA – Code of Ethics applicable to Promotional Practices of the Pharmaceutical Industry.

### 1.2 How is "advertising" defined?

Advertising of medicinal products is defined in Portuguese law as any kind of information, prospective or incentive activity, purported to, or that has the effect of, promoting the prescription, supply, sale or consumption of medicinal products in any of, but not limited to, the following situations:

(i) to the public;

(ii) to wholesale distributors and healthcare professionals ("HCPs");

(iii) through visits of medical sales representatives to the persons mentioned above;

(iv) through the supply of samples or commercial bonus to wholesale distributors and HCPs;

(v) through the grant, offering or promise of any benefit, either in cash or in kind, except when its intrinsic value is insignificant (less than 60 Euros);

(vi) through the sponsorship of promotional meetings attended by wholesale distributors and HCPs;

(vii) through the sponsorship of scientific venues attended by wholesale distributors and HCPs, and in particular the payment of their travelling and accommodation expenses; and

(viii) by the reference to the name of the medicinal product.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Companies have to provide Infarmed with the specifications of all advertising pieces used in the promotional activities of their medicinal products, within 10 days of the date of release of the relevant advertising.

Holders of marketing authorisations ("MAs") are required to have a scientific department led by a physician or pharmacist, which is responsible for the information and advertising of its medicinal products. The sign-off of all advertising initiatives is committed to this scientific body.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Apart from the obligations referred to in question 1.3 above, companies' scientific bodies responsible for the advertising of medicinal products have to implement the following SOPs:

(i) organise and keep record of all the advertising made by the company, and allow the consultation and access thereto by regulatory authorities within a period of five years;

(ii) assure that the advertising complies with all applicable legal requirements;

(iii) assure that the company's sales representatives have adequate qualifications and training; and

(iv) implement information systems aimed to assure the receipt and processing of data provided by sales representatives related to adverse events of the respective medicinal products.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No, the advertising of medicinal products does not have to be approved in advance by any authority.

However, the holders of MAs or companies in charge of the promotion and advertising of medicinal products have to provide

Infarmed with the specifications of all advertising pieces used within 10 days of the date of the relevant release.

Also, the holders of MAs shall keep the documentation related to the advertising available for consultation by competent authorities for a period of five years.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The Board of Directors of Infarmed have the power to compel MA holders to stop and/or correct any advertising made by them that is considered as being in breach of the applicable legal requirements. Furthermore, MA holders are bound to cooperate with the competent authorities in providing the necessary information for the purpose of performance of the relevant powers with respect to advertising.

Additionally, Infarmed may also open an investigation procedure of misdemeanour prosecution.

MA holders, or the entity responsible for the advertising at stake, are entitled to file their defence in the scope of the misdemeanour proceedings, where prevention measures or sanctions are applied by Infarmed, and also have the right to appeal therefrom. The appeal for the review of the decision has to be submitted to Infarmed. Infarmed's decision on any sanctions may also be challenged by judicial proceeding aimed at its impeachment.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The penalties consist of a fine that may range between 2,000 Euros and 15% of the turnover, or 180,000 Euros, whichever is lower, and other ancillary sanctions. The latter may be applicable in case of serious violations of advertising rules.

The ancillary sanctions may consist of the suspension of the authorisation or licence granted to the entity that has committed the infraction ("defendant") up to a period of two years, loss in favour of the State of objects and equipment used by the defendant, and prohibition to participate in public tenders for a period of up to two years. Also, the penalties can entail the publication of the conviction in the media and suspension, for a period of up to two years, of the advertising of the medicinal product at stake.

The entity responsible for the enforcement of these rules and procedures is the Board of Directors of Infarmed and the rules are enforced in a very strict manner. It is quite common, and usually upon the complaint of a competitor, for Infarmed to open misdemeanour procedures against pharma companies based on the breach of the advertising rules.

Notwithstanding the possibility of competitors taking action by filing a complaint to Infarmed based on the illegal advertising practices, a competitor may also take direct action in court against a company that it considers to be in breach of advertising rules, to file a claim for civil liability and/or unfair competition. In any of these situations, the claim will have to be sustained on the argument that the illegal advertising is causing severe damages to the competitor.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The Code of Ethics of Apifarma is a self-regulatory instrument and therefore, is only binding upon Apifarma members. However, the rules set forth in this type of instrument are consensual and followed by the majority of the pharma sector. For this reason, the competent authority, Infarmed, investigates matters that entail the breach of the Apifarma's Code provisions, and the rules set forth therein are considered as good practice standards of promotion of medicinal products.

Although Infarmed may not condemn any entity for breaching a rule laid down in the Apifarma Code that does not have a legal correspondence, the provisions set forth therein may be used as interpretative rules and as good practice standards to be considered in the analysis of a certain advertising infraction.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Any competition act that is contrary to the rules and honest standards of any economic activity, namely for misleading customers and the market with respect to features of the relevant products or making false statements purported to harm competitors' reputation, is considered unfair competition.

Unfair competition practices constitute a misdemeanour according to Portuguese law. A company that is impaired due to such type of practices may take action by filing a complaint to the Economic and Food Security Authority ("ASAE").

A company impaired by unfair competition acts may also claim before a judicial court for an indemnity envisaging compensation of the damages suffered from those acts against the economic operators at stake. The law also provides for injunctions that have to be approved by court, in order to allow protection against acts of unfair competition on a preliminary/urgent basis.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

These questions tackle the issue of separation between information and advertising of medicinal products, which often is not completely clear. Although it is accepted that pharmaceutical companies inform the scientific community about advances in the

field of medicinal products and therapeutics and disclose the outcome of the scientific research they are carrying out for that purpose, the advertising of unauthorised medicinal products is not allowed.

This principle is applicable in the same terms to off-label indications, where advertising is also forbidden.

The analysis of whether or not the organisation, sponsor or participation in a certain scientific meeting constitutes advertising or disclosure of scientific information shall be made on a case-by-case basis, taking into account many aspects such as the contents of the information itself, and the relationship between the speakers and the sponsor.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Information on unauthorised medicines and off-label indications may be published whenever it is not, directly or indirectly, purported to, or has the effect of, promoting the prescription, supply, sale or consumption of the relevant medicinal products. This situation shall also be evaluated on a case-by-case basis, taking into consideration the purpose of the dissemination of the relevant information, its contents and the relationship existent between the publisher of the information and the company responsible for the relevant product.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Apart from those referred to in question 2.2 above, it should be stated that if such press releases are considered as advertising, they would not be allowed, regardless of the audience they are addressed to.

In contrast, if the content of such press releases is effectively only informative, rather than promotional, it should be allowed.

As already commented, the situation has to be evaluated on a case-by-case basis, and for those purposes, the target audience may play an important role. In practical terms, if the target audience consists of specialised medical or scientific media, it shall be easier to justify the content of such press releases as merely informative, since it is acceptable for pharmaceutical companies to inform the scientific community about advances in the field of medicinal products.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

If information on a certain unauthorised medicine or off-label information is provided by the company responsible for such product to HCPs upon request of the latter, it may confirm that such supply of information does not envisage promotional purposes, in which case it shall not be considered advertising.

It should be noted that the law expressly qualifies information (rather than advertising) as the correspondence between companies and HCPs regarding questions on medicinal products, provided that it does not include any promotional content.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

In fact, this case did not cause much impact, probably due to the fact that Portugal does not have a system like in German law, that allowed pharmacists to obtain, in another State, medicinal products not approved in Germany, but lawfully introduced in the market in that other State. The use of non-approved medicinal products in Portugal is only allowed in very specific situations that always require authorisation from Infarmed to the hospitals or to the holder of the MA. The regulatory requirements applicable to compassionate use purposes of medicinal products are very strict, and therefore its supply does not entail a significant flow of sales through pharmacies.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

In principle, healthcare institutions must submit an annual request to Infarmed on the non-authorised medicinal products they will use in the following year.

The proactive supply of this information by manufacturers to healthcare institutions may be construed as advertising.

However, this kind of information shall be evaluated on a case-by-case basis in order to assure that it is information and not advertising. Moreover, costs reduction itself does not qualify as a legitimate reason to use or to advertise non-approved medicinal products.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

We believe that this is possible, provided that this collaboration of consultancy or advisory from HCPs is considered as inherent to the development of the company's activity, and does not fall within the concept of advertising activity of medicinal products as defined by law, or an indication not yet approved.

There are no guidelines on these matters.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Advertisements directed to HCPs must contain the following information:

(i) name of the product;

(ii) essential information compatible with the SmPC, namely:

- qualitative and quantitative composition;
- pharmaceutical form;
- therapeutic indications;
- dosage and administration;
- contraindications;
- undesirable effects; and
- special warnings and precautions for use and interactions with other medicinal products, if relevant from a clinical point of view;

(iii) the classification as a prescribed-only or non-prescription medicine; and

(iv) the reimbursement system.

Additionally, the advertisement pieces shall contain the following statement: "For more information, please contact the holder of MA."

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Besides the general rules mentioned above, advertising to HCPs shall be accurate, current, verifiable and complete in order to allow the HCP to have a correct idea of the therapeutic value of the product.

The advertising materials may refer to studies not mentioned in the SmPC, provided that those studies, or quotes from the studies, are true, accurate, current and verifiable. This means that companies shall make these studies available to HCPs and to authorities upon their request.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

There are no specific restrictions to the inclusion of an endorsement by HCPs regarding prescription-only medicinal products (endorsement by HCPs is not allowed for non-prescription medicinal products). However, these endorsements must comply with the rules on testimonial advertisements, which state that testimonial advertising is allowed whenever it is real and verifiable and related to the experience of the deponent.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

No. The only existing rules about comparative advertisements are those described in the answer to question 3.5 below.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

The general rule on comparative advertisements is that they are can only be viewed by HCPs, and therefore strictly forbidden to the public.

The comparative advertisement of medicines to HCPs is allowed, subject to the following rules:

(i) comparisons shall be based on relevant and comparable aspects between the medicines, and cannot be misleading or defamatory; and

(ii) comparisons between medicines can only be made based on elements disclosed in: (1) SmPC; (2) Technical Documentation; or (3) Credible Clinical Data.

Considering the above, it is possible to use another company's brand name as part of the comparison. With regards to the use of the competitor's product or an indication that has not yet been approved, this shall not be allowed once it is qualified as promotion of a product that does not hold an MA or off-label promotion of a medicinal product.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no specific rules on this matter. Therefore, and provided that the papers are in fact scientific articles, and proceedings of congresses that fully describe the content of scientific or medical presentations made in the congress, they are not qualified as advertisement materials, but as information.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Considering the requirements mentioned in question 3.1 above on the mandatory information of any advertisement of medicinal products before HCPs, it seems difficult that the accomplishment with such regulatory requirements may be compatible with a teaser. It should be noted that advertising of medicinal products has always to be identified as such.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

In case the combination of Products A and B is expressly mentioned, and consequently authorised by the competent authorities, in the Product A's SmPC, we are of the opinion that the MA holder of Product A could promote this combination of products. The fact that this combination is expressly foreseen and authorised in the SmPC, constitutes an on-label use and promotion of these products. Regarding the holder of the MA of Product B, in order to be safe, they shall firstly vary the SmPC to avoid any accusations of off-label promotion.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes, it is possible, following a prior written request by HCPs. The maximum number of samples to be provided to a HCP is four per year and only within two years of the date when the medicinal product starts to be effectively marketed.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

It is not possible to give, offer or promise to offer gifts or money to HCPs. However, giving benefits or objects up to 60 Euros that are relevant for the practice of medicine or pharmacy and/or involve a benefit for the patient, is allowed.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

It is possible to provide support, either financially or non-financially, to healthcare organisations, with the purpose of supporting healthcare services or research activities. The granting of the support shall be preceded by a written request of the beneficiary entity and it shall not constitute an incentive to the prescription and supply of medicinal products.

However, with the entry into force of a new law, establishments, services and hospitals of the National Health Service may only receive those gifts and donations from pharmaceutical companies if authorisation is granted by Infarmed, in order to ensure that the grant of such support is not deemed to jeopardise the exemption and impartiality.

Also, for public hospitals, there is another limitation on the receiving of this type of support. In cases of direct award for the acquisition of medicinal products, the contracting authority cannot invite a company to submit a tender, from which it has received, in the last two years, gifts, supply of services carried out free of charge, or equipment, except for gifts made under the Patronage Statute.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The rule is that the supply of informational or educational materials and items of medical utility may not be an incentive to the prescription, purchase, and administration or dispensing of medicinal products or a way of compensation for the latter. Considering this rule, and provided that granting medical or educational goods constitutes a benefit for the patient, if that situation leads to changes in the prescription patterns, it may be sustained that it occurred due to their benefits and not because the company was trying to encourage the prescription of its medicinal products or compensate HCPs.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

The rules on the advertisement of medicinal products are not applicable to commercial practices regarding prices and discounts.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

This type of offer and donation would most likely be considered as an incentive to the prescription, purchase, and administration or dispensing of medicinal products or a way of compensation to HCPs, and therefore they are not allowed.

However, it is possible to have commercial arrangements between pharmaceutical companies and hospitals, under which certain services related to the administration or use of the medicinal product at stake are rendered, provided that such services are also paid, even if its cost is included in the purchase price.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

That is not possible. The refund of medicinal products, prescription-only or not, may only occur within the specific situations and limits set forth in the Good Distributing Practice of Medicinal Products.

Nevertheless, it should be noted that this prohibition does not prevent the execution of risk-sharing agreements as foreseen in the reimbursement legal framework of medicinal products.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Pharmaceutical companies may sponsor medical education by granting sponsorships to events organised by third parties and may also support the hospitality costs of HCPs attending those educational events.

However, we believe that the sponsor of continuing medical education either to an entity or to a HCP may lead to the incentive of the prescription or supply of the company's products, which is not allowed.

Transparency disclosure requirements described in question 7.2 below are applicable to the sponsorship granted by pharmaceutical companies which includes the sponsorship of medical education.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The principles and general rules for the purposes of anti-bribery are established in the Portuguese Criminal Code. Infarmed, being the competent authority for pharmaceutical advertising, is responsible for investigating any breach of the advertising rules and the anti-bribery legislation. Nonetheless, in conducting these investigations, Infarmed cooperates with a wide range of entities.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The general rules that govern the offering of hospitality to HCPs by pharmaceutical companies, are the following:

(i) it shall be limited strictly to the main objective of the event;

(ii) it shall not be subject to the obligation of the HCP to prescribe any medicine;

(iii) it shall not be provided as a compensation for the time spent by the HCP in the participation of the event;

(iv) it shall not exceed the level that the HCP would be willing to pay, themselves, for participation in the event; and

(v) it shall not include the sponsor or the organisation of any leisure or entertainment events.

In principle, the events should take place in Portugal, unless it is logistically more reasonable to hold the event in another country. In these cases, we believe the rules in force in the country where the event takes place would be followed. However, if the rules of the country of residence of the HCP are stricter, these are applicable.

There is no threshold applicable to the costs of hospitality provided to a HCP, only the rules described in question 5.2 below. Regarding the cost of meals, they may not exceed 60 Euros (in case of a national meeting), or 90 Euros (in case of an international meeting).

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The costs related to travel, accommodation and enrolment fees for the attendance of HCPs in scientific meetings are reimbursable. The costs of accommodation shall only include the period between the day prior to the beginning of the event and the day after it ends. Regarding the expenses of meals, see question 5.1.

Payment to a HCP for his/her time in attending scientific meetings is not allowed.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

A pharmaceutical company may be held liable for the breach of advertising regulatory requirements, either with respect to hospitality arrangements, or to the sponsor of scientific meetings, in case the relevant breach derived from an act or omission of such company even if it has acted jointly with other parties.

The mere existence of any such agreement or sponsor of a scientific meeting does not automatically trigger the company's liability. The responsibility of the pharmaceutical company in those situations shall be evaluated on a case-by-case basis. In this assessment, one should take the following into consideration: the level of engagement of the pharma company in those events; the relationship between the HCP and the pharmaceutical companies; and the context of the messages disclosed in these events, in order to verify if the company can be responsible for any illegal advertisement.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes, provided that it does not result in an incentive or compensation for such HCP to recommend, prescribe, purchase or supply certain medicinal products.

The parties shall enter into a written agreement in order to specify the nature of the contract and identify the services to be provided by the HCP.

Additionally, the pharmaceutical company shall communicate to Infarmed any amounts payable to the HCP for the provision of expert services (or any grant, sponsorship, or any other value, which may be evaluated in cash), within a timeline of 30 days after termination of the event.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Yes, provided that it does not constitute an incentive for HCPs to recommend or prescribe certain medicinal products.

In this case, a written contract shall be executed between the HCP and/or institutions where the study will be developed and the sponsoring company, in which the nature of the services to be provided by the HCP and the reasoning for the payment of the relevant services, shall be specified.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes, it is possible, provided that it does not result in an incentive for the HCP to recommend or prescribe certain medicinal products.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, it is possible to advertise non-prescription medicines to the public if such medicines are not reimbursable by the National Health System.

Advertising to the public shall not include any information that:

(i) leads to the conclusion that no medical appointment or surgical procedure is necessary and that induces a certain diagnosis, or treatment by correspondence;

(ii) suggests that the effect of the medicinal product is guaranteed, with no adverse reactions or side effects, with results greater or equivalent to those of another treatment or medicinal product;

(iii) suggests that the person's normal health condition may be improved by the use of the medicinal product;

(iv) suggests that the person's normal health condition may be impaired in case the medicinal product is not used (except for approved vaccination campaigns);

(v) is exclusively or mainly targeted at children;

(vi) refers to a recommendation from scientists, HCPs or other persons, who because of their celebrity status may encourage the consumption of medicinal products;

(vii) suggests that the medicinal product is a food, cosmetic or personal hygiene product, or any other consumption product;

(viii) suggests that the safety or efficacy of the medicinal product is due to the fact that it is a natural product;

(ix) may lead to an erroneous self-diagnosis through a detailed description or representation of patient history;

(x) refers in inadequate, alarming or misleading terms to evidence or guarantee of recovery; and

(xi) uses inadequate, alarming or misleading terms, representations of changes in the human body or parts of the human body, caused by diseases or injury or of the action of a medicinal product.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

No, it is not possible to advertise prescription-only medicinal products to the general public.

Prescription-only medicinal products can only be advertised to HCPs under certain conditions.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are permitted if no reference, even if indirect, is made to any medicinal product.

These initiatives are permitted based on the grounds that the information is disclosed to the public in order to raise awareness for a particular medical condition, and to provide information that is valuable for the relevant patients. It does not constitute advertising of any product.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

It would be likely that such press releases would be considered advertising, which is not allowed for prescription-only medicines when addressed to the public and non-scientific journals being targeted at the general public.

Notwithstanding, press releases on developments in relation to unauthorised medicines or unauthorised indications are, in general, not allowed.

In both cases, if the contents of such press releases are effectively only informative, rather than promotional, it should be allowed.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Companies' institutional advertising, such as financial data, description of research and development programmes, corporate brochures and annual reports, does not qualify as the advertising of medicinal products.

However, if such institutional information includes contents related to specific medicinal products that are subject to medical prescription, it may be considered advertising to the general public, which is not allowed for prescription-only medicinal products.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There is a code of practice applicable to Apifarma members: the Apifarma Code of Conduct Governing the Relations between the Pharmaceutical Industry and Patients' Organisations.

Pharmaceutical companies are allowed to support patients' organisations and to sponsor meetings organised by said institutions provided that it is not an incentive for the recommendation of a particular medicinal product.

Transparency disclosure requirements set forth in the Medicinal Products Act are also applicable to any funding granted by pharmaceutical companies to patients' organisations.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The rule is that companies cannot provide patients with any items (such as prizes, offers, bonuses or cash benefits or in kind).

However, objects of insignificant value, defined as objects with a purchase cost for the pharma company that does not exceed 60 Euros, and that are relevant for medicine or pharmacy practice, may be supplied to patients through their HCP.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The clinical trials regulatory framework establishes certain information obligations for the sponsors, notably the registration of trials in the National Registry of Clinical Trials and report of the results to Infarmed.

Besides that, pharmaceutical companies may release information relating to clinical trials, subject to certain limitations.

If the company chooses to release information on clinical trials, such disclosure has to comply with the following requirements:

(i) its contents shall be in accordance with the observations and the results of the relevant study;

(ii) allow the verification of the observations made in the study, through the disclosure of the relevant scientific grounds;

(iii) indicate the members responsible for the study, notably the main investigator, the main sponsor and the centre of the study;

(iv) indicate any existing conflict of interests between the investigator, the sponsor and the centre of the study, if any; and

(v) indicate the funding sources of the study.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Yes. The holders of MAs and distributors of medicinal products shall inform Infarmed of the grant of any subsidies, gifts, supports, sponsorships or any other sum, asset or right with cash value, from 60 Euros, to any person or entity, namely to HCPs, patients' associations, healthcare service providers or medical and scientific societies.

Such obligation is accomplished by the upload of the relevant information on the transparency platform available on Infarmed's website within a 30-day period.

These reporting obligations only apply to entities that are subject to the Medicinal Products Act, namely holder of MAs, local representatives of marketing authorisation holders, manufacturers and wholesale distributors of medicinal products and/or entities responsible for information provision and advertising of medicinal products. Therefore, a company that acts in any of the mentioned capacities, even if it has not yet been granted a marketing authorisation, must comply with the reporting obligations.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

According to the Apifarma Code of Conduct Governing the Relations between the Pharmaceutical Industry and Patients' Organisations, the holders of marketing authorisations must publish on their institutional website their sponsorship of patients' organisations until May 31 each year.

Regarding companies that have not yet been granted a marketing authorisation, see question 7.2 above.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

An individual HCP, who has received transfers of value from a pharmaceutical company, is also bound to validate, even if tacitly, that fact to Infarmed. Thus, if such person refuses to make such validation/disclosure, the company shall comply with its obligation to report the relevant act on the transparency platform, and request the HCP to comply with its obligation too.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

There are no specific legal rules on advertising on the Internet, therefore, it is subject to the general legal framework applicable to the advertising of medicinal products.

The Apifarma Code foresees the obligation for companies to adopt specific measures in order to ensure that the advertisement of prescription-only medicinal products is only accessible through the Internet by HCPs. However, those measures are not specified.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

The Apifarma Code does not specify the level of website security required to ensure that the public does not have access to sites intended only for HCPs.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

There are no specific rules on these matters. Therefore, a company must ensure, or at least must not contribute to, access by the public to advertising of prescription-only medicinal products.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Pharmaceutical companies are allowed to make institutional advertising which may be published on their websites.

Moreover, pharma companies may place on their websites the respective medicines, as well as information on the characteristics of such products (namely official and approved documents, such as the SmPC or the Patient Information Leaflet). Any type of information regarding those products that may be deemed as promotional must observe the general rules applicable to the advertisement of medicines.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

No, there are not.

The legal concept of advertising of medicinal products includes communication released through any media, which includes social media.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

In January 2017, a new law was published, Decree Law 5/2017, approving the general principles of medicinal products and medical devices advertising, which had a great impact on the relationship between pharma companies and hospitals and other entities from the National Health Service.

The new law adopted the following measures:

(i) Prohibition on hospitals and services of the National Health System on receiving financial benefits or benefits in kind from pharmaceutical and medical devices companies, except if those actions do not undermine the services exemption and impartiality and are authorised by the Health Minister. The authorisation procedure has not yet been defined, nor has the criteria to evaluate exemption and impartiality.

(ii) Prohibition on hospitals and services of the National Health System on carrying out promotional and scientific actions sponsored by pharmaceutical and medical devices companies. Contrary to the prohibition referred to in (i), in this case there are no exceptions foreseen. This will lead to a discussion of what is considered to be the promotion of medicinal products and what is simply information.

(iii) Facilitation of the communication procedure to Infarmed by HCPs who receive benefits from the pharmaceutical industry, now only requested to validate the information submitted by the pharmaceutical industry to Infarmed on that matter.

Following the impact caused by these measures, especially that which prevented public hospitals from carrying out scientific meetings and events at its premises, the Government has made a U-turn, and it is now possible to organise scientific events at hospitals, provided that authorisation is granted by Infarmed.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

There are fields that need to be further developed, namely off-label promotion, access to information of prescription-only medicinal products by the public, and advertisement on the Internet.

Once the medicinal products regulatory framework is harmonised through European legislation, we believe that the national legislator will only approve any further statutes on this matter upon the implementation of EU directives.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

Our national agency, Infarmed, has a very conservative interpretation of the definition of advertisement of medicinal products. Therefore, often this agency qualifies as advertising most information released by pharmaceutical companies to the public and also most interactions with HCPs.

It should also be noted that, recently, promotional activities for food supplements have been relevant for many reasons, notably for advertising products that are often confused with medicinal products. This trend led to the approval of guidelines related to borderline products by administrative entities with authority on medicinal products and food safety ("ASAE" and "DGAV"). It is expected that better coordination between such entities will provide more effective law enforcement against abusive promotional practices in this field.

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Joana provides regular legal assistance to pharmaceutical companies, cell and tissue banks, especially in regulatory areas and in what regards the marketing of health and pharmaceutical products. She also provides legal assistance in biotechnology projects and to start-up companies, as well as to medical devices distributors.

She gives advice on clinical trials and issues related to the protection of personal data and due diligence exercise, restructuring transactions and merger and acquisitions operations in the healthcare sector.

She was admitted to the Portuguese Bar Association in 2005.

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# Slovakia

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ČECHOVÁ & PARTNERS s. r. o.

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The following laws govern the advertising of medicinal products:

- Act No. 147/2001 on Advertising, as amended (the "**Advertising Act**"); and
- Act No. 362/2011 Coll. on Medicinal Products and Medical Devices, as amended (the "**Act on Medicinal Products**").

Further, the following codes of conduct are relevant for advertising medicinal products:

- Code of Conduct of the Association of Innovative Pharmaceutical Industry ("**AIFP**") (the "**AIFP Code of Conduct**"), binding for the members of AIFP, is the Slovak member association of the European Federation of Pharmaceutical Industries and Associations ("**EFPIA**") associating innovative pharmaceutical companies (currently having 32 member companies);
- Code of Conduct of GENAS – the Association of Generic Manufacturers ("**GENAS**") (the "**GENAS Code of Conduct**"), binding for the members of GENAS, is the association of manufacturers of generic medicinal products (currently having 16 member companies) and a member of the European generic association Medicines for Europe; and
- Advertising Practice Code of Ethics issued by the Advertising Council – the association of ethical self-regulation of advertising; the Advertising Practice Code of Ethics is only binding for the member companies of the Advertising Council, which do not include any pharmaceutical companies, nevertheless, the Advertising Council enjoys wide authority and its decisions are often followed as best practices even by non-member companies.

### 1.2 How is "advertising" defined?

The Advertising Act defines advertising as a demonstration, presentation or other communication in any form related to a commercial, business or other profit-making activity in order to market products.

Advertising of medicinal products is defined as including any form of door-to-door information, agitation or aim to promote the prescription, dispensing, sale or consumption of medicinal products.

Advertising of medicinal products includes:

(a) advertising medicinal products meant for the public;

(b) advertising medicinal products meant for persons authorised to prescribe and to dispense medicinal products;

(c) a visit from a person authorised to prescribe or to dispense medicinal products by a medical representative with the aim of promoting medicinal products;

(d) providing samples of medicinal products to the public, persons authorised to prescribe medicinal products and persons authorised to dispense medicinal products;

(e) providing incentives to prescribe or dispense medicinal products, such as gifts, offers or promises of any benefit or extra financial or in-kind consideration, with the exception of those which value is negligible;

(f) sponsoring promotional events (this provision is obsolete as such events are not possible anymore) in which persons authorised to prescribe or to dispense medicinal products participate; and

(g) sponsoring scientific congresses in which persons authorised to prescribe or to dispense medicinal products participate, including a reimbursement of travel expenses and accommodation costs associated with participation in the event.

On the other hand, the following activities do not constitute as advertising medicinal products:

(a) medicinal products labelling and patient information leaflets ("**PIL**");

(b) correspondence, which may be accompanied by a non-promotional material, necessary to answer a specific question relating to the medicinal product;

(c) reference material and information relating, for example, to a change in the packaging of a medicinal product, to adverse effects warnings within the medicinal products supervision, or a business catalogue and price list provided that it contains no information about medicinal products;

(d) information relating to human health or disease, if it does not contain a direct or indirect reference to a medicinal product;

(e) publication of information on Internet dispensation, offered range of medicinal products and medical devices, their price and costs associated with Internet dispensation according to a special regulation;

(f) publishing of information regarding the use of medicinal products, their prices, replacement generic medicinal products and contraindications and interactions or an electronic application that includes information about medicinal products, their prices, generic replacement medicinal products and contraindications; and

(g) publishing information containing only the name and price of the medicinal product(s).

AIFP and GENAS Codes of Conduct define advertising for the purpose of the respective codes as the presentation of a medicinal product in any form with the goal to apply it in the market, including any form of door-to-door information, agitation activity or aim to promote the prescription, dispensing, sale or consumption of medicinal products, as well as claims relating to effectiveness, rate of adverse events, or other warning aspects of medicinal products and comparative information.

The Advertising Practice Code of Ethics contains a wider definition of advertising, which potentially contains also non-promotional, educational activities, being a communication process initiated by a competitor or a person designated by them, as well as the content resulting from this communication process, if (a) this communication process is performed for remuneration or another value, or (b) the purpose of this communication process is to anyhow influence the behaviour of a consumer, in particular to provide a consumer with information about a product, activity or goals of a competitor, or its charitable or non-commercial project. Therefore, non-promotional, awareness and educational activities of pharmaceutical companies are also subject to the scrutiny of the Advertising Council.

**1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?**

Based on the Advertising Act, a marketing authorisation holder is obliged, among others, to create a scientific service responsible for the information about the medicinal products it is marketing, and to provide for the compliance of advertisement of medicinal products with the requirements of the Advertising Act.

The legislative provisions are mirrored by AIFP and GENAS Codes of Conduct, based on which the member companies shall establish a medical department (which may also serve as the scientific service). This department must include a person responsible for the approval of any advertising material before its release. This person shall confirm that they verified the final form of the advertising material, and that the latter complies with the provisions of the respective Code of Conduct and applicable laws, is in accordance with the Summary of Product Characteristics ("**SmPC**") and is a correct and true demonstration of the facts about the medicinal product.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

The Advertising Act, AIFP and GENAS Codes of Conduct indirectly require the introduction of internal approval mechanisms, since they require each advertising material to contain the information on the date of approval or updating of the material; however, no further details as to the content of the SOPs are given.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

No, prior approval by a regulatory or industry authority is not required, save for vaccination campaigns for the general public, which requires the prior approval of the Ministry of Health of the Slovak Republic, since vaccination campaigns constitute an exemption from the general prohibition of promotion of prescription products to the general public. The law further requires a marketing authorisation holder to make available or to provide to the state supervisory authority – the State Institute for Drug Control (the "**SIDC**") – a sample of each advertisement released by the company, together with the information on the audience of the advertising, the method and commencement date of its release.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The SIDC may prohibit the further dissemination of advertising in case it breaches the provisions of the Advertising Act, and to impose an obligation to publish its decision and a corrective statement in mass media. Such decision may be appealed to the Ministry of Health, and subsequently reviewed by the court.

The Ethics Committee of AIFP may review the compliance of its members with the AIFP Code of Conduct, either based on a complaint, or from its own initiative. In case of non-compliance, the Ethics Committee may impose an obligation of public apology and impose fines on its members. In the case of continuous non-compliance of a member, the Ethics Committee may suspend the membership of such member or even expel the member from the AIFP. The decision of the Ethics Committee may be appealed to the appellate body – the Supervisory Board of AIFP, being the supreme body of the association. Similar rules apply in GENAS.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

A breach of the provisions of the Advertising Act may be sanctioned by the SIDC by fines of up to EUR 166,000. Based on publicly available decisions and information, fines are typically in thousands of euros and for more significant breaches around EUR 10,000–30,000.

The Ethics Committee of AIFP may impose a fine of up to EUR 20,000 on AIFP members for a breach of the AIFP Code of Conduct. GENAS may impose fines of up to EUR 9,000 (in the case of a repeated infringement) for breaches of the GENAS Code of Conduct.

The Advertising Council does not impose sanctions – it merely declares a breach of the Advertising Practice Code of Ethics and publishes, or sometimes also medialises, its decision.

Apart from complaining to the SIDC in case of alleged breaches of the Advertising Act or to the industry association in the case of an alleged breach of the respective Code of Conduct, a competitor may file a direct lawsuit against an entity, in case the advertising constitutes an act of unfair competition (e.g. by misleading advertising, misleading the designation of goods or services, etc.). The available claims include cessation of the conduct, remedying of the situation, and financial satisfaction, damages and payment of unjust enrichment.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The state regulatory authorities, in particular the SIDC, only supervise compliance with the law. Conversely, the industry associations (AIFP, GENAS) only supervise compliance with their respective codes of conduct. It cannot be excluded that in case of a serious finding, an industry association may inform the state authorities, or a state authority pro-actively takes up a matter based on learning a finding by a self-regulatory body, however, both situations rarely occur in practice. Conversely, the state authorities may theoretically investigate matters vetted by the industry associations.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Under Slovak law, the breach of the Advertising Act does not automatically constitute a breach of unfair competition rules, although some overlaps may occur, e.g. in case of misleading advertising.

If the breach of rules on unfair competition is established, the competitor or another person whose rights were breached (e.g. a consumer association) may seek remedy under the unfair competition rules, including refraining from the unlawful conduct, to eliminate the improper state of affairs, to provide appropriate satisfaction, including in money, and to demand compensation for damage and the restitution of unjust enrichment.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Advertising of medicinal products that are not authorised (do not have a marketing authorisation) in the Slovak Republic is in general prohibited by the Advertising Act. The law also states that this prohibition does not apply to advertising to persons authorised to prescribe and dispense medicinal products, however, this provision is in general considered a legislative error by incorrect reference as a result of multiple amendments to the applicable provisions.

AIFP and GENAS Codes of Conduct strictly prohibit any advertising of non-authorised medicinal products or off label advertising of authorised medicinal products outside its approved indications.

The only exception allowed by the AIFP Code of Conduct (compatibility of which with the law is, however, questionable, since the Advertising Act does not contain a corresponding exemption) relates to international professional events organised in Slovakia, attended by a majority of foreign participants. During such events, the exhibition of or provision of educational information on medicines not authorised in Slovakia, or an indication not approved in Slovakia, is acceptable, provided that the product or indication in question is authorised in the country the foreign congress attendees come from, while every used exhibited or educational material shall expressly state that it relates to the product or indication not authorised in Slovakia, and that the product or indication is authorised abroad. Information relating to such product shall be in accordance with the SmPC of the product as approved in the country where the product is authorised.

Non-authorised products may be discussed with the healthcare professionals on a strictly professional, non-promotional basis. Based on the Advertising Act, correspondence, which may be accompanied by a non-promotional material, necessary to answer a specific question relating to the medicinal product, does not constitute advertisement, and is, therefore, not covered by the prohibition of off-label advertising.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Information on unauthorised medicines or an off-label indication may be published only provided that it is non-promotional and clearly falls outside the definition of advertising, e.g. in the case of a clearly non-promotional publication in a scientific journal.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

As the advertising of unauthorised medicinal products is prohibited, press releases may be published only if they fall outside the definition of advertising and are generally of a non-promotional nature. In most cases this would not be met, as a local press release is likely to have a primarily promotional motivation, since e.g. scientific- or stock-exchange-related reporting duties occur most of the time elsewhere and do not justify the need of a local press release.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

A proactive communication on this topic, e.g. highlighting positives of an ongoing medicine development, would be very likely to constitute advertising. Information on unauthorised products or off-label indications may be sent to healthcare professionals only exceptionally if it does not constitute advertising. One of the negative definitions of advertising of medicinal products is correspondence, which may be accompanied by a non-promotional material, necessary to answer a specific question relating to the medicinal product. Therefore, if the information is requested by a professional, it can be provided, under the strict condition that it solely answers the specific question and does not contain any promotional claim.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The negative definition of advertising under the Advertising Act includes the business catalogue and price list, provided that it contains no (further) information about medicinal products. Therefore, provision of the price list, even containing unauthorised products, would not be considered advertising, if no further information about the product is included. It must be said, however, that that would rarely be the case in practice, since named-patient/compassionate use programmes are usually applied on a case-by-case basis, and are not reflected in standard price lists.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Yes, communication with the authorities is generally accepted as not falling under the restrictions of advertising laws.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Yes, under the strict conditions that such involvement of healthcare professionals does not factually entail an advertising towards those healthcare professionals or other prohibited activities (which might be difficult to achieve in practice since the engaged healthcare professional would have to be acquainted with the potentially promotional materials).

Pursuant to the AIFP and GENAS Codes of Conduct, similar exercises would likely fall under the category of "other studies" (other than clinical trials and non-interventional clinical studies), which are permitted, provided that they do not concern effectiveness or safety of particular medicinal products, and which may include e.g. marketing research to ascertain the quality of performance of the research sponsor. Marketing studies and research cannot be promotional and connected to the prescription or recommendation of any products of a company.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

According to the Advertising Act, an advertisement directed at healthcare professionals shall contain:

(a) basic information on the medicinal product that is consistent with the SmPC;

(b) the classification of the medicinal product according to its dispensation (OTC/Rx); and

(c) the date of the document or of its latest update.

Further, if the advertising is in the form of the document handed over to a HCP in the context of promotion, it shall contain accurate and up-to-date information that is verifiable and sufficiently comprehensive to enable the recipient to form their own opinion on the therapeutic value of the advertised medicinal product. Tables of prices or other tables and illustrations taken from the medicinal journals or other scientific works that are used in the documentation must be correctly reproduced and must state the exact source.

Under the AIFP and GENAS Codes of Conduct, the advertisement shall contain a full or short summary of the product information. The full summary of the product information is the approved and applicable (up-to-date) version of the SmPC for the Slovak Republic. The short summary of the product information may be used in medical publications. It must accurately reflect the full product information, while it may be a paraphrase or summary of the full product information. Wherever required, product information must appear in a type size of not less than 2 mm on a background sufficiently contrasting for legibility. Major headings should be easily identifiable. Product information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Apart from the general requirements for any advertisement under the Advertising Act (e.g. not to be offensive, discriminatory, violent, etc.), advertising of medicinal products:

(a) shall be fully in accordance with the SmPC;

(b) shall support the rational usage of the medicine by the objective information on its characteristics, without exaggerating its characteristics; and

(c) shall not be deceptive.

According to the guidelines published on the website of the SIDC (derived from EU case law), advertising of medicinal products may only contain information supported by their SmPC. In the case of studies, it means that only the studies taken into account in their SmPC, or studies further specifying them, may be mentioned, while the information must be compatible with and must not distort the information in the SmPC and the studies mentioned therein. Advertising for healthcare professionals may contain information adopted from professional publications, which shall be exactly reproduced and referenced and compliant with their SmPC.

The AIFP Code of Conduct states that healthcare professionals may request the literature about the matters not addressed in the SmPC, e.g. off-label indications. It is unacceptable for such literature to be freely disseminated without prior request. It is acceptable to provide such information upon the individual request of a healthcare professional.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

The law does not regulate endorsements by healthcare professionals in promotional materials for healthcare professionals (as compared to the advertising of medicines for the general public, where endorsements are prohibited).

AIFP and GENAS Codes of Conduct require that physicians' names or photographs are not to be used in any way that is contrary to medical ethics. Promotional endorsement may be contrary to the requirement of independence and impartiality of healthcare professionals.

The Advertising Practice Code of Ethics prohibits endorsements by any particular individual or representative of a legal entity who could, based on their position or profession, influence the consumption of medicines.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Comparative claims must be in line with the general requirements for comparative advertising under the Advertising Act.

The AIFP and GENAS Codes of Conduct require that a claim of comparative efficacy or safety must not be based solely on a comparison of information from the SmPCs; this applies to Slovak as well as foreign SmPCs.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Pursuant to the Advertising Act, a comparative advertisement is admissible only provided that it:

(a) compares products that are designed for the same purpose;

(b) objectively compares one or more concrete, typical, essential and provable properties of the products including their price;

(c) does not discredit or libel trademarks, business names or other distinguishing factors, products or circumstances of the competitor;

(d) does not unfairly take the advantage of the reputation of a trademark, business name or other distinguishing features of a competitor or designation of origin of a competitor's products;

(e) does not present the product as an imitation or a copy of products which is protected by a trademark or business name;

(f) does not create a mistaken identity between businesses, between an advertiser and a competitor or between trademarks, business names, other distinguishing features, products or an advertiser and a competitor; and

(g) is not misleading.

The comparative advertising of medicines to the general public is prohibited.

The AIFP and GENAS Codes of Conduct require that the comparison of products must not be misleading or disparaging and that it must be factual, fair, based on relevant and comparable aspects of the medicinal products and be capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission of an important attribute or property or in any other way. Comparisons which merely claim that a medicinal product is better, stronger or more widely prescribed, etc. must not be used. Comparative claims on efficacy or safety shall be reasoned regarding all aspects of efficacy and safety of the product. If a comparative claim is related only to a specific parameter, this must be clear from all claims. Special rules apply to references to data without statistical importance.

Referring to another company's brand name is possible if the above rules are complied with.

The AIFP and GENAS Codes of Conduct prohibit references to a competitor's product or indication, which have not yet been authorised in Slovakia.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no specific rules in the legislation. If the materials are distributed in a promotional context, the general rules of advertising apply, in particular the requirement for conformity with the SmPC, objectiveness and veracity. The provision of materials having an appreciable financial value may be subject to the withholding tax (see question 4.1).

Under the AIFP and GENAS Codes of Conduct, the contents of any reprints of scientific papers, proceedings of congresses or summaries of literature used in advertising must always be consistent with the SmPC of the medicinal product and it is not acceptable to routinely disseminate such literature where unsolicited on subjects not covered by the SmPC, such as non-approved indications.

Medical educational materials shall be authorised and contain the name and local address of the manufacturer or sponsor. If promotional claims are included, the material no longer qualifies as educational. Information and educational materials cannot recommend, prescribe, or encourage the purchase, supply, sale or administration of a particular medicinal product.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Slovak law does not regulate teaser advertisements. However, teaser advertisements may not be feasible for medicinal products, since each advertisement for healthcare professionals shall, under the Advertising Act, contain certain mandatory information (see question 3.1).

Similarly, the AIFP and GENAS Codes of Conduct require advertisements to contain certain mandatory information, in particular a short or full summary of product information, which would be difficult to achieve in the case of a teaser advertisement.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

The described situation is not regulated in Slovak law or the applicable Codes of Conduct. Applying the general principles of the Codes of Conduct prohibiting the promotion of off-label use, it seems that the MA holder of Product A would be permitted to mention its use in combination with Product B, provided that it follows from the SmPC of Product A; however, the MA holder of Product B would not be permitted to promote the off-label usage of

Product B for Product A's indication due to the limitations of Product B's SmPC. However, it cannot be excluded that should a similar case be subject to the scrutiny of the authorities or industry associations, a different approach may be selected.

## 4 Gifts and Financial Incentives

### 4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Yes. Under Section 8(19) of the Advertising Act, the MA holder may, upon written request, provide samples of medicinal products to a healthcare professional in the maximum amount of two samples of the smallest available packaging per year, provided that these are labelled as a sample and not for sale and with the enclosed SmPC.

Under the AIFP and GENAS Codes of Conduct, samples must not be supplied in order to encourage the recommendation, prescription, purchase, supply, sale or administration of the specific medicinal products and shall not be supplied for the sole reason of the patient treatment. Samples must not be supplied as donations. Further, under the AIFP Code of Conduct, samples may be supplied only within the first two years after the first placement of a medicinal product on the market, or within two years since the respective healthcare professional has obtained their licence.

However, the practice of providing samples became very limited in Slovakia from 2015, following the introduction of the legislation based on which any financial or in-kind consideration provided to a healthcare professional, healthcare organisation or its employee by a MA holder, medicines manufacturer, wholesaler, pharmaceutical company, pharmacy, or a third person intermediating such consideration is, save for certain exemptions, subject to a 19% withholding tax. The tax authorities are interpreting the withholding income tax to apply to provisions of samples as well, although this does not have a clear legal basis.

### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

No gifts, financial or in-kind advantages or benefits may be given, offered or promised to healthcare professionals in the context of the advertising of medicines, pursuant to the Advertising Act.

A similar restriction applies under the AIFP and GENAS Codes of Conduct, which also prohibit the supply, offering and promising of gifts, financial advantages or benefits in kind to healthcare professionals in order to encourage the recommendation, prescription, purchase, supply, sale or administration of a medicinal product. Gifts for the personal benefit of healthcare professionals must not be offered or provided.

Any potential gifts or donations would be subject to withholding tax.

### 4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

Gifts and donations to healthcare organisations are not prohibited as such. However, MA holders shall not, via such gifts and donations, incite, encourage or otherwise influence in any form, directly or indirectly or through a third person, the prescribing physician.

Similarly, under AIFP and GENAS Codes of Conduct, the gifts or donations are permitted only to non-profit organisations and state hospitals and are only allowed if:

(a) they are made for the purpose of supporting healthcare or research;

(b) documented and kept on record by the donor or grantor, and

(c) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a specific medicinal product.

There are no monetary limits that apply, however, any such gifts and donations are subject to the withholding tax.

### 4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

Based on the Act on Medicinal Products, a marketing authorisation holder is not allowed to in any way, directly, indirectly or through a third person, instigate, incite or otherwise influence a prescribing physician in their prescription of medicines. Therefore, this restriction shall be taken into account, while generally the provision of medical or educational goods or services is accepted in case of legitimate need or medical justification, i.e. where the goal is not to influence prescribing patterns.

Under the AIFP and GENAS Codes of Conduct, an educational material cannot induce recommendation, prescription, purchase, supply, sale or administration of the specific medicinal product.

### 4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

No regulatory restrictions apply. Under the interpretation of the law of the tax authorities, individualised discounts without economic justification may constitute an in-kind consideration subject to the withholding tax. Also, competition law rules shall be taken into account.

### 4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?

No gifts, financial or in-kind advantages or benefits may be given, offered or promised to healthcare professionals in the context of the advertising of medicines. Provision of additional services or equipment would likely be subject to the withholding tax. If the providing company is in a dominant position in the respective relevant markets, conditional sales and package deals may constitute an abuse of dominance by tying and bundling.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Refund schemes are not expressly prohibited, however, they may in practice constitute donation of medicines, which is subject to the withholding tax (applicable both to prescription-only and OTC medicines) and further restrictions under the AIFP and GENAS Codes of Conduct (applicable only to prescription-only medicines).

A refund scheme based on which the pharmaceutical company would cover the costs of ineffective treatment could theoretically be established by a risk-sharing agreement with a health insurance company. If offered to healthcare organisations for reimbursed prescription medicinal products, such refund schemes would possibly be in conflict with the reimbursement system, since the healthcare organisation would be refunded for the product, which is paid for by the health insurance company.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes, pharmaceutical companies may sponsor the continuing medical education and participation of professionals therein. The law only permits the sponsorship of professional events dedicated exclusively to professional, scientific or educational purposes for healthcare professionals. Accompanying activities cannot exceed 20% of the overall time of the event, excluding the time for travel and accommodation.

Sponsorship of professional events is subject to detailed rules of the industry associations.

In-kind consideration consisting of participation of a healthcare professional in an accredited continuing medical education event (excluding the value of travel and accommodation), and hospitality in a professional event dedicated exclusively to an educational purpose, is exempted from the withholding tax.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

General anti-bribery laws under the Penal Code prohibiting the criminal offences of active and passive corruption apply. The healthcare system may be considered a "matter of general interest", in connection of which the sanctions for corruption offences are stricter.

Anti-bribery rules are enforced by the police and prosecution authority under the rules set by the Penal Code for the criminal offences of corruption. Further, bribery may constitute an unfair competition conduct under the Commercial Code, enforced before general courts by the affected competitor.

Supervision of advertising by the SIDC and of anti-bribery laws by the police and prosecution authority do not overlap.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Pharmaceutical companies are only allowed to support the attendance of a healthcare professional in a professional event dedicated solely to a scientific, professional or educational purpose. Hospitality must be limited to the main purpose of the event.

The AIFP and GENAS Codes of Conduct contain detailed rules about hospitality, which must be limited to covering the costs of travel, accommodation, food and attendance fees. Hospitality may be provided only to qualified healthcare professionals, and cannot be extended to before or after the official duration of the event.

Social events may be organised only outside the official programme of the event and cannot be covered from the attendance fees or from the sponsorship of pharmaceutical companies.

The same rules apply for attendance in foreign professional events. In general, pharmaceutical companies are required not to organise or sponsor foreign events, unless:

(a) the majority of the invitees comes from outside of the Slovak Republic and, given the countries of origin of the majority of the invitees, it makes greater logistical sense to hold the professional event in another country; or

(b) given the location of the relevant resource or expertise that is the object or subject matter of the professional event, it makes greater logistical sense to hold the event in another country.

All foreign professional events shall be notified to and consulted with the local affiliate of the pharmaceutical company in the country were the event is held, save for the events organised by professional societies. International events organised by the parent company of AIFP or GENAS member company from abroad are subject to the local Codes of Conduct.

All forms of hospitality cannot exceed the "appropriate" rate and must be strictly limited to the main purpose of the event. As a general rule, only the costs that the healthcare professionals would be otherwise willing to cover themselves can be covered. The AIFP Code of Conduct limits the value of hospitality offered in the form of meals to the amount of EUR 75 per the main course (lunch/dinner), EUR 100 for an all-day meal in Slovakia, and EUR 100 for the main course abroad; if hospitality is offered abroad, and the host country where the professional event is held has adopted its own limitations on hospitality, such limitations applicable in the host country shall prevail.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

It is allowed to support the attendance of healthcare professionals in professional events. Under AIFP and GENAS Codes of Conduct, reimbursement of costs of travel, accommodation, enrolment fees and food is permitted, although, payment for the time spent at the event is not.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Pharmaceutical companies will be held liable by the authorities if they sponsor anything other than the professional event or the attendance of a healthcare professional in anything other than their professional event. The fine imposed by the Ministry of Health ranges from EUR 500–25,000. Further, violations of the Advertising Act may occur through an event sponsored by a pharmaceutical company, e.g. if the scientific content is deemed actually as a hidden advertising. Such violations are sanctioned by fines of up to EUR 166,000, depending on the infringement, by the SIDC.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Paying healthcare professionals for export services is not prohibited under Slovak law. However, if such healthcare professionals are in a public role, which binds them by conflict of interest restrictions, this may create a reporting duty for them or exclusion from decision-making on the matters of the entity for which they acted this way.

Under AIFP and GENAS Codes of Conduct, a written agreement shall always be concluded prior to the commencement of the provision of such services; members are prohibited to use, in any manner whatsoever, agreements on works performed out of employment (a special employment law instrument for short term employment). A legitimate need for the services has to be clearly identified by the member in advance of requesting the services and entering into an arrangement with the prospective providers.

Remuneration for the services is subject to the withholding tax.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

Pursuant to the Act on Medicinal Products, healthcare professionals may be entitled to reimbursement of time and costs incurred in connection with a performance within a post-authorisation safety study. PASS studies cannot be performed if their goal would be to support usage of the product.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

In general, yes. Under the AIFP Code of Conduct, remuneration of a healthcare professional for cooperation in market research has to be in accordance with the work performed and it may not exceed the usual amount with respect to the character of the work done. Under the GENAS Code of Conduct, the remuneration cannot exceed ⅟₁₀ of the minimum monthly wage per one hour (i.e. in 2019, EUR 52 per hour). Remuneration for participation in market research may be subject to higher scrutiny due to risks of it being a payment or remuneration for other services or favourable treatment.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, non-prescription medicines can be advertised to the general public. Advertising to the general public cannot:

(a) create an impression that a medical examination or procedure is useless;

(b) offer a finding of a diagnosis or treatment by correspondence;

(c) create an impression that effects of a medicinal product are guaranteed and without adverse effects or they are better or equal than the effects of another product or treatment;

(d) suggest that good health may be proved as a result of taking medicines;

(e) suggest that good health may be influenced by not taking medicines (excluding vaccination campaigns);

(f) approach exclusively or mainly children;

(g) contain endorsements from scientists, healthcare professionals or famous persons;

(h) liken a medicine with a foodstuff, cosmetic product or other consumer product;

(i) create an impression that the safety or effectiveness of a medicine is based on it having a natural origin;

(j) lead, as a result of a description of anamnesis, to wrongful self-diagnosis;

(k) overly, alarmingly or deceptively refer to the confirmation of healing a disease; and

(l) overly, alarmingly or deceptively use depictions of changes of human organisms as a result of a disease or injury and depict the effect of a medicine on these changes.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

No, advertising of prescription-only medicines to the general public is prohibited, save for vaccination campaigns approved by the Ministry of Health.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns are generally accepted in practice as far as they do not constitute advertising. Similar projects may fall under the negative definition of advertising: information relating to human health or disease, if it does not contain a direct or indirect reference to a medicinal product.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Press releases regarding prescription-only medicines may be issued in a non-scientific journal only provided that it does not promote such medicine, i.e. constitute advertising, which would be difficult to achieve in practice.

Under AIFP and GENAS Codes of Conduct, commercial names of prescription-only medicinal products and active substances cannot be mentioned in communication to the general public.

Information provided to the media has to be used exclusively for improvement of public knowledge in the health and medical area, not for the promotion of medicines. Such information about new chemical substances, new medicinal products and ways of treatment delivered to the public and media:

(a) has to be truthful, verified, full, clear and understandable;

(b) must not contain any unproved assumptions and expectations;

(c) must not create a false illusion for patients about treatment efficacy or unverified hope for certain improvement of their health status; and

(d) has to be free of intention to mislead a journalist or a patient or intention to damage a competitor.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

There are no specific rules. This type of information may be included in corporate brochures or Annual Reports as long as it does not factually constitute advertising and does not have such intent. In case of Annual Reports mandatorily published by certain companies, the risk would be very minor.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Relationships with patient organisations are not regulated by the law, but is extensively covered by the AIFP and GENAS Codes of Conduct. All findings must be based on written agreements and published annually. Patient events and hospitality are subject to similar, albeit simpler, rules than those involving healthcare professionals.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Only direct distribution of medicines to the public for advertising purposes is explicitly prohibited by law. The provision of items should be reviewed on a case-by-case basis to ensure it does not constitute unlawful advertising of prescription-only medicines.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

All clinical trials must be approved by an ethics committee and the SIDC, which maintains the database of trials. Termination of a clinical trial shall be reported to the SIDC and the respective ethics committee within 90 days (or within 15 days in case of early termination). Information and documentation of a clinical trial shall be disclosed to the SIDC, the respective ethics committee, and the health insurance company of a participating study subject upon request.

Specific disclosure obligations relate to non-interventional clinical studies (observation and evaluation of usage of a medicine in clinical practice other than a PASS), protocols and results of which shall be provided to the SIDC, which shall publish them online, and to the health insurance companies of participating study subjects. Non-interventional clinical studies shall also be reported to the industry associations under their respective Codes of Conduct.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Marketing authorisation holders, medicinal products manufacturers, wholesalers, pharmacies and local representations of pharmaceutical companies are obliged to disclose all financial and in-kind considerations provided to healthcare professionals and healthcare organisations (but not to patient organisations) to the SIDC within the report on marketing expenditures. Companies that have not yet been granted the respective authorisation are not affected by the obligation. Foreign companies are subject to the obligation as long as their authorisation covers Slovakia (e.g. MA holders of medicines centrally authorised by the EMA).

The information is included in the comprehensive marketing expenditures report submitted to the SIDC electronically on the prescribed form twice per year, and include the identification of the recipient, amount and purpose of the financial or in-kind consideration, and the related medicinal product, if applicable.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The AIFP Code of Conduct requires the disclosure of transfers of value to healthcare professionals and healthcare organisations from the member companies derived from the EFPIA Disclosure Code; however, these were largely rendered obsolete by the introduction of the similar obligation by the legislation. Similar rules on disclosure of engagements of and transfers of value to healthcare professionals and patient organisations apply under the GENAS Code of Conduct. Disclosure under the legislation, results of which are published by the SIDC, is considered to meet the requirements of the AIFP Code of Conduct. Similarly, the GENAS Code of Conduct transparency rules do not apply in the extent covered by local legislation.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

Disclosure is obligatory based on the law, which does not require the consent of a healthcare professional. In case of disclosure beyond

the scope of law, where consent is the legal basis, such consent needs to be fully voluntary and should not be forced. In the absence of such consent, the publication of aggregate or anonymous data may be an option.

## 8 The Internet

### 8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet advertising is subject to general advertising rules. The online sale of medicinal products is limited to non-prescription products, which limits the practical reach of online advertising. The AIFP and GENAS Codes of Conduct contain special rules for website transparency, content, privacy, e-mail communication and links.

### 8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

The AIFP and GENAS Codes of Conduct require the information for healthcare professionals to be clearly designated as such, however, they do not require further encryption or restriction.

### 8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Under AIFP and GENAS Codes of Conduct, links from company-sponsored sites for the general public shall not lead to independent websites for healthcare professionals. The same rules apply *vice versa* – links to company-sponsored sites for healthcare professionals shall not be created on independent websites for the general public.

Links to independent websites should lead to the homepage so that the reader is aware of the identity of the website.

According to the e-commerce legislation, a service provider is not liable for the information provided by a service recipient and saved upon its request to the memory of electronic devices serving for the searching of information (e.g. to links to third-party websites), provided that the e-commerce service provider does not know about the unlawful content of the information or the unlawful conduct of the service recipient, and acts without undue delay to remedy the unlawful state; the e-commerce service provider is, however, fully liable for the information if the service recipient acts based on the service provider's instructions.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Based on the legislation, websites for the general public may in general contain the advertisement permitted to the general public, e.g. the promotion of OTC products and vaccination campaigns approved by the Ministry of Health.

Based on AIFP and GENAS Codes of Conduct, company websites for the general public may contain general company information (e.g. information for investors, media and public, including financial information, research and development programmes and information for potential employees), health education information (non-promotional information on diseases, prevention, screening and treatment with a mandatory recommendation to consult a professional), and other non-promotional information for the general public (e.g. the current list of products manufactured or distributed by the company, including the SmPC and PIL for each product). This is without prejudice to the possibility to state the information permitted by the law (e.g. approved vaccination campaigns).

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There are no specific legal or local industry regulations.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The last significant development was the adoption of mandatory disclosure of transfers of value in 2016, and introduction of the withholding tax in 2015, which rules were further modified and provided guidance on in the following years. Minor changes to the AIFP Code of Conduct, relating, among others, to promotional materials and market research, were introduced in March 2019.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No significant developments are currently announced.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Enforcement in the field of pharmaceutical advertising is actively taking place within the industry associations and their self-regulatory instruments. Enforcement by the state authorities as seen in the last few years occurs in cases of evident and significant breaches or active complaints from other stakeholders.

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# Spain

Cecilia Pastor

Ester Navas

Baker McKenzie

## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

**Laws**: From an advertising standpoint the main law is the General Advertising Law 34/1988 (the "Advertising Act"). From a regulatory standpoint the basic rules on advertising of medicinal products are to be found in Royal Decree 1416/1994, which governs advertising of medicines for human use. The content of this Decree has been further explained through Circular 6/95 issued by the General Directorate of Pharmacy and Medical Devices and today the Medicines and Medical Devices Agency. Certain provisions contained in the Law on Guarantees and Rational Use of Medicines and Medical Devices, approved by the Royal Legislative Decree 1/2015 (the "Law on Guarantees") are also relevant with regard to the advertising of medicinal products in Spain.

In addition to the above, the laws of Spain have increasingly displaced responsibilities over health matters to the various Autonomous Communities into which the Spanish territory is divided. Consequently, depending on the area in which the advertising or promotion takes place and/or the location of the corporate headquarters of the pharmaceutical company advertising or promoting its products, the complementary and interpretative legislation developed in the appropriate Autonomous Community must also be taken into consideration.

**Codes**: Back in 2002, pharmaceutical companies belonging to Farmaindustria (the Pharmaceutical Industry's National Business Association) adopted a new Spanish Code of Ethics for the Promotion of Medicines initially aimed at healthcare professionals, which entered into force on July 2002, replacing its 1993 Code (the "Farmaindustria Code"). The latest consolidated version of the Farmaindustria Code of October 2016 also includes transparency obligations.

Reference must also be made to the Code of Ethics of the National Association of OTCs (ANFEP) on the promotion of OTC medicinal products. Furthermore, the Ministry of Health published a Guide on the advertising of OTC medicinal products in April 2011 that includes a code on the promotion of medicinal products to the general public (the "OTC Guide").

### 1.2 How is "advertising" defined?

Section 1 of Royal Decree 1416/1994 includes all of the following as advertising of medicines: the advertising of medicines to the general public; the advertising of medicines to those qualified to prescribe or dispense them; visits by medical sales representatives to those qualified to prescribe or dispense medicines; the distribution of free samples; the sponsorship of promotional meetings attended by those qualified to prescribe or dispense medicines; the sponsorship of scientific congresses attended by those qualified to prescribe or dispense medicines and, in particular, the payment of their travelling and accommodation expenses in connection therewith; and inducements to prescribe or dispense medicines by gift, offer, or promise of any benefit, in cash or in kind, except when their intrinsic value is minimal.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The Farmaindustria Code requires companies to have in place an internal monitoring written procedure for compliance with the Code and that all information related to medicinal products marketed by a company must be managed by a scientific service.

Having said this, both the company and the scientific service according to the Royal Decree 1416/1994, must comply with certain obligations such as revising and controlling any promotional materials in order to ensure compliance of the medicinal products with the legal requirements and that the information they contain complies with the marketing authorisation and SmPC. They must also ensure that they compile all information regarding the medicinal products marketed, which includes maintaining a registry of the requests for and supply of medicinal product samples. Additionally, they are obligated to ensure adequate training for the medical sales representatives and all personnel involved in the promotion of the medicinal products and all the professionals or healthcare patient organisations. Finally, they must supply the health authorities with the assistance or information that might be required and guarantee full compliance and fulfilment of the decisions of the relevant health authorities.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Yes. Companies are required to set up and maintain internal monitoring compliance written procedures that focus on compliance

with the Farmaindustria Code. Additionally, companies are required to appoint at least one employee or manager with sufficient qualifications who will be responsible for internal oversight of compliance with the Farmaindustria Code. There are no specific rules in the Farmaindustria Code related to the specific qualification of such compliance officer. In any case, the companies may appoint a single person, several persons or a committee that jointly decides how activities are to be performed and that compliance with the Farmaindustria Code is internally verified. The Farmaindustria Code also encourages the entire company (that is to say, every department, division, etc.) to be involved and participate in the committee and internal procedures implemented by the company in order to meet compliance objectives. In all cases, the existence of persons responsible for internal supervision does not exempt the company's senior officers from responsibility.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

Advertising of medicinal products addressed to individuals with the ability to prescribe or dispense does not require prior approval by the industry authority. However, companies must send copies of the advertisements to the competent Health Authority of the Autonomous Community where the company is located and must ensure that access to such advertising is limited to the qualified individuals. The foregoing is without prejudice to the possibility of the Ministry of Health subjecting, on an exceptional basis, advertising of specific medicinal products to prior approval.

As of July 2013, administrative authorisation is no longer required when advertising over-the-counter (OTC) medicines addressed to the general public.

Additionally, companies must send an annual index with all its advertising activities to the Health Authority of the Autonomous Community where the company is located.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Health authorities are responsible for enforcing compliance with legal provisions governing the advertising of medicines. Within the framework of available procedures for infraction and in general terms, health authorities may temporarily suspend advertising or may request that corrective action be taken. Beyond this, if the advertisement constitutes a risk for the health and security of consumers, health authorities can order the publication of the resolution confirming such risk and can also order the publication of a corrective statement where the advertisement was published. An appeal may be lodged against the resolution issued.

The foregoing actions are without prejudice to the possible application of certain remedies such as cessation and rectification that are available to the competent authorities under the Unfair Competition Act and the Advertising Act.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

In general terms, a breach of the provisions of the Royal Decree 1416/1994 constitutes an administrative offence and is subject to administrative fines ranging from 6,000 Euros to 1,000,000 Euros (this amount could be increased in case of recurrent offences), levied at the discretion of the health authorities of the relevant Autonomous Community, taking into account the negligence or intentionality of the violator, fraud or collusion, non-compliance with previous warnings, the company's business volume, the number of persons affected, damages caused, profits earned from committing the infraction, and permanence or transience of risks.

It is also worth noting that breach of advertising rules may lead to criminal liability. In this respect, the Spanish Supreme Court set a precedent in its judgment of 2001 which resulted in convictions for the administrator and employee of a laboratory and for a NHS doctor.

The Farmaindustria Code establishes infringements, which could lead to a mere warning or to fines from 6,000 Euros up to 360,000 Euros and to the provisional or definitive expulsion from Farmaindustria. Member companies of Farmaindustria are required to first go through the complaints procedure established by the Code before filing any claim before the courts or the health authorities.

In general terms, the most important examples of actions against pharmaceutical companies are those taken by Farmaindustria or by competitors and decided by the Jury of Autocontrol (see below) when applying the Farmaindustria Code.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The Farmaindustria Code maintains and enforces control mechanisms to ensure application of the Code. It has done so by setting up an Ethics Surveillance Unit, an Ethics Committee (known as Code of Practice Committee) and by submitting disputes to the Jury of Advertising, which is a specialised body within the Association of Self Regulation of Advertising (known as Autocontrol), with the ability to adjudicate disputes and impose fines. The relationship between the self-regulatory process and the supervisory and enforcement function is mainly the fact that the Code states that the claims against the advertising practices of other companies must be brought before the Ethics Committee of Farmaindustria before being raised with the health authorities or the Courts.

It is important to note that if a claim or an issue is being dealt with or evaluated by a competent Court or a health authority, the Jury of Autocontrol must refrain from intervening or taking on that claim or issue.

Finally, the competent authorities can, and do in practice, initiate an investigation even if they are being evaluated by any self-regulatory body, and they could also undertake matters based on any finding or conclusion of any self-regulatory body.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

According to the Law on Guarantees, any breach of the Advertising Act shall be considered an unlawful act under the Unfair Competition Act. Actions for breach of advertising rules and actions for unfair competition have been unified to avoid any inconsistencies and include: actions of cessation or prohibition; actions of declaration of unlawfulness; actions of removal of effects; and actions of rectification. Such actions may be brought by any third party who is affected by the unlawful advertising.

By way of example, if the infraction of the regulations entails a significant market advantage for the offending pharmaceutical company, any competitor (understood to mean any person acting in the market whose economic interests have been directly damaged or threatened) may legitimately file suit for unfair competition. Based on such suit, the competitor may request, among other actions, the removal of the effects caused by the offending act and compensation for damages caused by the offending act, if wilful misconduct or negligence were involved. Compensation may include publication of the sentence.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

As a general principle, Royal Decree 1416/1994 states that the advertising of a medicine that has not obtained the corresponding marketing authorisation is prohibited. This prohibition, as mentioned in the Farmaindustria Code, cannot involve a limitation to the right of the scientific community to be informed about scientific and medical progress and cannot be directed to restrict the complete and suitable exchange of scientific information related to medicines, which includes the objective and suitable spreading of discoveries of scientific researches through scientific media and in scientific meetings.

Hence, it is important to establish a difference between information and advertising. Such difference will depend on the purpose conveyed. Any information purporting to promote (conveyed with a view to promote…) the prescription, offer, sale or the use of medicinal products will be deemed as advertising. In this regard, any new information in connection with a medicinal product should be broadcast/published/given without being linked to advertising and promotional aspects, in other words, providing the original published articles, without advertising of the product.

Additionally, it should be pointed out that, in the framework of international congresses of acknowledged prestige and importance held in Spain attended in significant numbers by professionals of other countries, the Catalonian Guide, for example, understands that it is possible to engage in the advertising of medicines and indications not authorised in Spain but authorised in the countries represented in the congress. In these cases, the fact that the medicinal product or indication is not authorised in Spain must be clearly stated and all the documents must be drafted in the language of the country where the medicine is authorised or in English.

Regarding off-label information, the Royal Decree 1015/2009 of June 19, governing the use of medicinal products in special situations, determines that any marketing authorisation holder must refrain from promoting off-label medicinal products and must also refrain from distributing any type of material or information that could directly or indirectly lead to a use of the product for obtaining results or in conditions that are different than those approved and explained in the SmPC.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

The publication in scientific media of information prior to authorisation would be acceptable if such publication is not deemed to be an advertising activity. In this sense, the following actions have been deemed to be information as opposed to advertising: journalistic information provided by journalists as part of their professional services, in regular editions, supplements, extraordinary numbers or editions of diaries, magazines, TV programmes, radio, etc. in which it appears as news, interview, debate, editorial, etc.; information related to pharmacotherapy; relevant treatments; relevant new specific medicines; scientific studies or research; and references to any medicine and research line or launching of a product, provided there is no contractual relationship between the pharmaceutical company and the publishing company or the journalist.

Additionally, the Jury of Autocontrol has taken into account all of the following when assessing the existence of advertising activity: (i) the limited journalistic importance of the news; (ii) the laudatory tone of the supposed information; (iii) the origin of the information in a press release issued by the pharmaceutical company which distributes the promoted medicine; (iv) non-simultaneous media coverage; and (v) the location of the information in the journal. The only information that can be provided (upon prior request) that is not promotional must be objectively and appropriately of genuine scientific interest.

However, the information on unauthorised medicines and/or off-label information is not acceptable for publication.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Yes. But it is important to note that the press release must not have a promotional nature. It must also not derive from any sort of agreement with a media company or publishing company. The press releases may only be about matters of legitimate interest to shareholders, employees, possible investors or other interested parties in the company's well-being.

In essence, the possible release will depend on whether the release could be construed as information or as advertising. Given that the release (i) would originate in the company, as opposed to an unrelated third party, and (ii) would refer to a specific product, as opposed to the company itself, (presumably with an emphasis on the merits of the product), it is probable that if contested, and based on the precedents to date from the Jury of Autocontrol, it would be construed as a case of indirect product advertising geared towards generating expectations in the recipients as from such time as the product is authorised. Such indirect advertising for unauthorised medicines or off-label information is prohibited irrespective of the target audience.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Please refer to question 2.3 above. Please also note the exception to the advertising of products which are not yet authorised in international congresses mentioned in question 2.1 above.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The ECJ judgment in the *Ludwigs* case is not specifically applied or reflected in any Spanish legislation. Nevertheless, Royal Decree 1416/1994 does state that any price list for medicinal products will not be considered illegal advertising if said price list does not contain information regarding a medicinal product.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Taking into consideration that the general principle is the prohibition of any kind of advertising of products which are not yet authorised, the exceptions to such principle must be restrictively interpreted. It would be difficult to argue that the sending of information to institutions to enable them to plan ahead in their budget for products to be authorised in the future is not a promotional activity but a way to inform the scientific community on scientific and medical progress. Accordingly, it could be construed as advertising.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Yes. It is possible to involve healthcare professionals in market research and other such exercises as long as the applicable legal requirements are met. According to the Farmaindustria Code, market research studies require all of the following: that the study does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products; that the studies be approved prior to their conduction by the scientific service or by the compliance officer; that the sales network of the pharmaceutical company does not play any role in the conduct and implementation of the study; that there be a written protocol of the objectives, methodology that will be applied, the expected results and use; and any written agreements be signed with the professionals and/or the entities that will carry out the study, specifying the nature of the provided service, the compensation and it's conditions (payments must be made in cash, based on market criteria and proportionate to time invested, results). And finally, that the data collected is processed jointly and that the results of the study are not advertisements or used as promotional material.

The studies must be previously communicated to the Surveillance Unit of Farmaindustria who can also approve exceptions to the abovementioned requirements. The communication to the Surveillance Unit of Farmaindustria is not required when: the sponsoring or financing of the company does not exceed 50%; or the company lacks access to the identity of the healthcare professionals who participate in the study in any way; or when the study does not imply payment of compensation to the participants or compensates less than 20 healthcare professionals.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

In advertising to persons qualified to prescribe or dispense medicines the necessary technical-scientific information must be provided for them to be able to decide, on their own account, the therapeutic value of the medicine and must include at least the following: the essential product information, as per the data contained in the technical data sheet; name of the medicine; qualitative and quantitative composition; complete clinical data; incompatibilities; directions for use/handling; and name and address of the authorisation holder; how it is to be prescribed and dispensed; the different presentations of the product, if appropriate, and the dosage and/or pharmaceutical form; the recommended retail price; the conditions for benefits within the National Health System to apply; and, whenever possible, the estimated total cost of the treatment.

Documentary advertising must additionally include the date on which such documentation was drawn up or last reviewed.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Generally speaking, the Farmaindustria Code requires that studies and information be quoted in the exact manner that they have been approved and any statistic or graphics must be reproduced literally. The information that appears in an advertisement must always be precise and adequate to allow the scientific evaluation and the therapeutic value of the medicinal product. Advertisements may refer to studies that have not been included in the SmPC, only to the extent that said studies do not contradict the information provided in the SmPC.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Yes. Any inclusion of endorsements by healthcare professionals in promotional materials, based on the Farmaindustria Code must reflect the exact opinion of the author and cannot be used without their previous consent. Endorsements by healthcare professionals must not have an economic interest behind them.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

No. There are no specific legal requirements related to the necessity of "head to head" clinical trials before comparative claims can be made. Nevertheless, all advertising must comply with the principle of objectivity which entails specific requirements to provide health professionals with the necessary technical/scientific information for them to be able to decide, on their own account, the therapeutic value of the medicinal product, and specially related to the use of results obtained by clinical trials as the basis of such advertising. Consequently, such comparative claims must be duly based on clinical trials referred to the medicines under comparison or to other similar medicines (medicines with exactly the same composition, or generic medicines) but in this latter case, with an express reference to such circumstance.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

The Advertising Act states that comparative advertising is deemed to be unfair when it is not based on essential and similar characteristics of the products or services, which cannot be objectively proven, or when the products or services subject to comparison are not similar or one of them is unknown or has a limited participation in the market. In this sense, the Farmaindustria Code has stated that comparative advertising cannot be degrading and comparisons must be based on comparable and notable circumstances.

Any information, statement or comparison included in promotional materials must be duly supported, and must be made available at the request of the physicians or the other health professionals and always to the health authorities. Specifically, any comparison made between medicines must be scientifically contrasted.

Provided that the above-mentioned requirements are complied with, it would be possible to use another company's trademarks or brand names of medicines specifying that they are owned by such company.

Comparative advertising of a competitor's product which has not yet been authorised in Spain would be difficult to support to the extent that no factual support will be available in Spain, and, in any event, it would be subject to the limitations explained in question 2.1 above.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The distribution of scientific papers and/or proceedings of congresses to physicians will be limited to the extent such papers and proceedings qualify as advertising as opposed to information. Royal Decree 1416/1994 provides, in this regard, that information regarding human health or illnesses/diseases shall not qualify as advertising insofar as no reference is made, even indirectly, to a medicinal product. Similarly, the Farmaindustria Code establishes that scientific papers published in well-known scientific media shall not fall under the notion of advertising provided they do not contain or are not linked in any way with any trademarks, trade names or advertising material of a medicinal product.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

There are no specific rules applied to "teaser" advertisements. Nevertheless, pursuant to Royal Decree 1416/1994, the aim of advertising to health professionals is to inform them about the characteristics of the relevant medicinal product. Consequently, taking into consideration that "teaser" advertisements are exclusively aimed at creating expectation, it would be difficult to qualify them as permissible advertising practices.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

As per a resolution of the Jury of *Autocontrol* dated February 14, 2019, when a company promotes the use of a medicinal product in combination with another medicinal product, such promotion must be in line with the SmPC of both medicinal products. Therefore, in the case at hand, neither the holder of the MA for Products A nor the holder of the MA for Product B may promote the combination use until such time as the holder of the MA for Product B varies the SmPc for Product B.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Spanish law considers the distribution of free samples as an exceptional promotional activity and therefore limits the kinds of

medicines that can be promoted this way, the recipients of such promotion and the duration of the promotional activity. Each sample should be clearly marked with the wording "sample – not for resale".

Free samples must be delivered directly to the health professionals qualified to prescribe, or to the persons duly authorised by the above, therefore excluding distribution to persons qualified to supply medicines. In addition, the Autonomous Communities tend to additionally regulate the distribution of free samples in public healthcare centres.

Only industrially manufactured pharmaceuticals and medicines which contain substances with new therapeutic indications or with new pharmaceutical preparation, form or manner of administering can be given out as free samples.

However, even those medicines which meet the above requirements may not be given out as free samples if they contain psychotropic or narcotic substances or cause dependence. The Ministry of Public Health and Consumer Affairs may also expressly exclude certain medicinal products.

As with other promotional activities of medicines, the distribution of free samples may only be engaged in after obtaining the corresponding authorisation, and is limited in time and number.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Royal Decree 1416/1994 expressly prohibits giving, offering, or promising to persons qualified to prescribe and supply medicines, within the framework of promoting medicines, bonuses, monetary advantages or advantages in kind, with the exception of those of insignificant value and those which are relevant to the practice of medicine or pharmacy.

Giving money is expressly prohibited under any circumstances regardless of the amount. With respect to giving gifts, (i) the value of the gift must be insignificant, (ii) it must be relevant for the practice of medicine or pharmacy, and (iii) it must directly benefit patient care. Consequently, objects not intended for professional use by the recipient are excluded.

The authorities have given no indication as to what constitutes an insignificant amount. The Farmaindustria Code specifies that the value of a gift should not exceed 60 Euros.

The Farmaindustria Code also allows to provide to healthcare professionals, stationery, or items for the practice of medicine or pharmacy that meet the following conditions: (i) is not related to a prescription-only medicine; and (ii) the market price does not exceed 10 Euros.

The above limitations are applicable to the promotion of medicines. If it is the general image of the pharmaceutical company which is being promoted, without referring to specific medicines, the above limitations do not apply. However, it must be borne in mind that there are limitations imposed due to the fact that the vast majority of prescribing physicians are part of the National Health System and are therefore civil servants. Likewise, there must be no direct relation or association between the image of the pharmaceutical company and any specific medicines.

Finally, incentives given to family members of persons qualified to prescribe or supply medicines are also prohibited.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

The prohibition of Royal Decree 1416/1994 described in question 4.2 above is aimed at health professionals and not at institutions. Therefore, the giving of gifts or donations to institutions is outside the scope of the prohibition and will be admissible insofar as it is geared towards the advancement of a scientific purpose, is to the benefit of patients, is to be used by the institution and is not aimed at the private use of a prescribing physician and is documented in writing. In other words, it serves a general, as opposed to a private, interest. In practice, it is quite common for donations to be channelled through institutions with a charitable status such as foundations. No monetary limits apply.

In any event, donations cannot be utilised as undercover inducements for the recommendation, prescription, purchase, supply, sale or administration of medicinal products.

Any gifts or donations to healthcare organisations will fall under the transparency obligations of the Farmaindustria Code explained in question 7.3 below.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Yes, if based on objective and scientific grounds. However, the provision of medical or educational goods and services to a healthcare professional cannot be made for the sole purpose of changing the prescribing patterns.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

The Law on Guarantees allows reasonable volume-related discounts and discounts for early payments for supplies to pharmacy offices, provided such discounts do not exceed 10% in the case of medicinal products financed by the NHS, do not induce the purchase of one product over a competing product and are reflected in the invoice. Supplies to public hospitals fall under public procurement rules.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

The prevailing principle is that the purchase of a product should be made on the grounds of its merits, in the best interests of patients and not in view of financial inducement. In addition, the Farmaindustria

Code expressly prohibits pharmaceutical companies to make any donation (of money, goods or services) to institutions, organisations, associations or foundations when it constitutes an inducement to recommend, prescribe, purchase, supply, sell or administer medicines.

Therefore, the free provision of services and equipment should, in principle, be unrelated to the purchase of medicinal products.

There is an exception to these cases, in which the provision of such services or equipment is expressly required under the terms of a tender with a public contractor entity as an improvement of the offer (*variante*). In these cases, such services or equipment must be directly related to the purchased medicine in order to be acceptable.

With regard to "package deals", they are acceptable to the extent the price of the associated benefit is a part of the purchase price of the medicinal product and, therefore, the provision or delivery of such associated benefit may not be considered a donation.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

This possibility is not contemplated under Spanish law.

According to the document Queries (questions and answers) on the interpretation of the Farmaindustria Code (the "Questions and Answers Document"), refund schemes related to medicines to be sold by pharmacy offices do not comply with the Farmaindustria Code.

With regard to medicines to be sold to hospitals, a refund scheme would be possible. As such, schemes are not provided for under Spanish law, there are no specific conditions to be observed. There should be no differences between whether the product is a prescription-only medicine or an OTC medicine, although such schemes are usually offered for prescription-only medicines.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

In practice, it is quite common for companies to fund fellowships and scholarships. These are frequently channelled through institutions with a charitable status, i.e. foundations. In any case, Farmaindustria requires pharmaceutical companies to adopt, in all cases, all measures necessary to avoid their collaboration in educational activities and initiatives constituting an inducement to the recommendation, prescription, purchase, supply, sale or administration of medicines.

When geared at individuals, as opposed to institutions, Farmaindustria has stated that it is possible for companies to finance or offer training courses to Spanish physicians on clinical topics or professional skills provided that the course is justified and actually helps to improve the professional training, and that the cost, location of the event and its duration is reasonable. Please refer to section 5 below on hospitality.

In particular, according to the Questions and Answers Document, pharmaceutical companies, prior to making a decision about the appropriateness of collaborating or not in this type of educational activity shall at least assess the following internally: (i) the prestige, rigour, seriousness, duration, cost and contents of the activity, as well as the usefulness it represents to the continued medical education of the healthcare professional, it being advisable that it belongs to a programme with a credit recognition system; and (ii) its compliance with the Farmaindustria Code and current legislation.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The law on Guarantees includes certain rules directed to assure the independence of the healthcare professionals and the pharmaceutical companies. Nevertheless, the real general anti-bribery rules are included within the Spanish Criminal Code approved by Organic Law 20/1995 (the Criminal Code). According to the Criminal Code, it is prohibited to bribe healthcare professionals when they are public officials (*cohecho*) and, since 2010, also when they are not public officials (*corrupción en los negocios*). There is no relationship between the competent authorities for pharmaceutical advertising and the prosecutor (supervising anti-bribery authority). We are not aware of any case in which the prosecutor and, subsequently, the criminal courts have investigated advertising materials previously assessed by the pharmaceutical authorities or Farmaindustria, but in theory it is possible.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Spanish law allows pharmaceutical companies to sponsor scientific meetings, congresses, courses, prizes, and grants, subject to certain requirements and limitations. Sponsorship activities do not require prior authorisation or communication to health authorities. Nevertheless, Farmaindustria members are required to comply with the transparency obligations mentioned under section 7 below.

The notion of sponsorship includes hospitality offered, directly or indirectly, within the framework of exclusively professional and scientific events, whether it is a congress or any other type of scientific meeting. Likewise, contributions or subsidies toward prizes, grants, meetings or congresses, and travel for study purposes fall into the category of sponsorship. Sponsored activities must be exclusively scientific and professional, and may be organised by the pharmaceutical company or by an external company. The essential element is the scientific and professional level of the event, which gives rise to the hospitality. Invitations outside said activities are, as a consequence, not permitted, if directed to the promotion of medicines.

The notion of hospitality includes travel and accommodation expenses paid for by the pharmaceutical company. According to the Farmaindustria Code:

- hospitality must always be moderate (the cost must not exceed the cost the recipients would be willing to pay in the same circumstances) and subordinate to the main purpose of the meeting;
- hospitality may not be extended beyond what is reasonable for conducting the relevant event (it may only be extended to the day after or before the event), nor may it include sponsorship or organisation of entertainment activities;
- the scientific content must take up the majority of the duration of the event with a minimum of 60% of each working day;
- travel times to the location where the event takes place will be adjusted to the duration of the scientific meeting;
- payments must not be made to healthcare professionals or groups of healthcare professionals, either directly or indirectly, to rent rooms for meetings unless it is duly accredited that the payments are for meetings of a scientific or professional nature;
- the location of the meeting should be chosen taking into account ease of travel of the participant, cost, appropriateness and appearance of the place;
- the recipients of such hospitality may only be healthcare professionals qualified to administer, prescribe or dispense medicines;
- no monetary reimbursement can be made to the healthcare professional for expenses incurred to suppliers that should have been paid directly by the pharmaceutical company, except in the case of minor costs for travel; and
- a maximum cost of 60 Euros (including taxes) per guest applies for any form of hospitality associated with meals. For events that take place outside of Spain, this is the maximum threshold established by the National Association of the country where the event occurs will apply.

Moreover, Spanish pharmaceutical companies shall ensure compliance by their parent company, subsidiaries and other related companies if the promotional activities are directed to healthcare professionals performing their services in Spain, whether invited to foreign countries or to other events in Spain. In these cases, it would not be necessary to have the hospitality approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place, but it would be advisable.

Additionally, the Farmaindustria Code states that pharmaceutical companies must not sponsor meetings abroad unless reasonable: (i) because of the number of foreign physicians participating in the meeting; or (ii) if there is an important expertise or resource to be found in the relevant country. In these cases, Spanish pharmaceutical companies must comply with both Spanish and local laws.

Inspection of prizes, grants, and contributions and subsidies to congresses, travel grants, and similar items may be scrutinised by the Autonomous Communities.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The Farmaindustria Code establishes that reasonable fees and expenses, including travel expenses, may be paid to those healthcare professionals participating as speakers or moderators at scientific meetings. In order to determine the reasonable nature or otherwise of the fees, it is necessary to take into consideration the fair market price and the time of the services effectively provided. Mere attendance at a congress, symposium or professional or scientific meeting are not considered as a professional service and, therefore, it is not possible to pay healthcare professionals for merely attending the event.

Regarding travel grants for participation in congresses, it is necessary that the pharmaceutical company handles registration procedures directly, in order to ensure the use of the grant for the purpose sponsored. The provision of cash advances to the healthcare professional is not allowed.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

A pharmaceutical company may be held responsible for the contents of and the hospitality arrangements for a scientific event if such event has been organised and/or mainly sponsored by such pharmaceutical company.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Healthcare professionals may render advice or counselling services (including participating in advisory boards), to the extent that contracting such healthcare professionals does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a given medicine and are subject to the following requirements:

- execution of a prior written agreement that specifies, at least, the nature of the services to be provided and the criteria for calculating the remuneration (which must be monetary – payments in kind may only be accepted exceptionally upon prior authorisation of the Surveillance Unit of Farmaindustria – and follow market criteria and be in accordance with the time spent, the work performed and the responsibilities assumed);
- actual legitimate need for the services;
- direct relationship between the criteria used to select the consultants and the identified need, and the expertise of the engaged healthcare professional; and
- maintenance of a documentary support of the services provided by the consultant and use of these services for the planned purpose.

If the pharmaceutical company engages more than one healthcare professional for the provision of services, the number of such healthcare professionals contracted must not exceed the number that would be reasonably necessary to achieve the planned objective.

Agreements with healthcare professionals for the rendering of services must be previously approved by the pharmaceutical company's scientific department or by the employee or manager appointed by the company for internal oversight of compliance with the Farmaindustria Code.

Farmaindustria members are required to comply with the transparency obligations mentioned under section 7 below.

In addition, and to the extent that the healthcare professional may be a civil servant, there will be additional restrictions on the grounds of

compatibility, to ensure that the physician's work as a public practitioner is not adversely affected by any private activities. In essence, under Spanish law, doctors employed by public hospitals may only have a private practice/activity to the extent compatible with his/her public activity. Compatibility is never presumed.

### 5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

Post-marketing surveillance studies consist of any clinical or epidemiological study conducted during the commercialisation of an authorised medicine according to the conditions authorised on its summary of product characteristics, or under normal usage conditions, in which the medicine is the fundamental exposure factor being investigated.

Post-marketing surveillance studies are governed by Royal Decree 1344/2007, of 11 October 2007, governing the pharmacovigilance of medicinal products for human use. The Royal Decree prohibits those studies whose aim may be to promote the prescription of medicines, and establishes that the health authorities, within the scope of their duties, must provide guidelines on the conditions under which such studies must be carried out, in order to favour those with a real scientific interest and to prevent those with purely promotional purposes. Such guidelines are set forth in Order SAS/3470/2009 of 16 December 2009.

Healthcare professionals who take part in such studies may be paid directly by sponsors. Nevertheless, in practice, the sponsor pays all the relevant costs to the centres or the foundations managing the studies and the relevant hospital or foundation pays the healthcare professional. Usually, the study agreement executed by the sponsor and the centre or foundation includes a representation of the sponsor related to the inexistence of any agreement under which the sponsor has assumed an obligation to directly pay any additional amount to the healthcare professionals taking part in the study. If, as per the agreement with the centre or foundation, the pharmaceutical company must pay the healthcare professionals directly, the requirements mentioned under question 5.4 above must be complied with. Additionally, the Farmaindustria Code requires that these studies must be conducted with a primarily scientific or educational purpose and must not be undertaken as means to promote a product or induce prescription.

### 5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

According to the Farmaindustria Code, market research (including social and opinion research) consists of the systematic compilation and interpretation of information on individuals and organisations using statistical and analytical methods and social science techniques that are applied in order to obtain new perceptions or to provide elements that support decision-making. Such market research must comply with the European Pharmaceutical Market Research Association (EphMRA) Code of Conduct.

Additionally, together with certain mechanisms that guarantee the appropriate execution of these studies, the Farmaindustria Code has specified the requirements to be complied with in order to avoid such studies representing an inducement to prescribe, or to possibly contain an incentive that is prohibited under the Code. In particular, among others, there is a requirement to have a written protocol that clearly establishes the objectives, methodology, anticipated results and use, and to remunerate the participating healthcare professionals following market criteria and in accordance with the time spent, the work performed and the responsibilities assumed. All other requirements mentioned under question 5.4 above must be complied with.

## 6 Advertising to the General Public

### 6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes. It is possible to advertise non-prescription medicines to the general public, provided that it is clear that the message is an advertisement and that the product is clearly specified as a medicine and provided that the advertising conforms with the content of the marketing authorisation. Such advertisements must include the minimum requirements mentioned in the Law on Guarantees and in Royal Decree 1416/1994.

There are certain specific restrictions forbidding certain indications such as: any mention that medical consultation or surgery is superfluous; any suggestion that the effects are guaranteed, that there are no side effects, or that the product is superior or equal to other treatment or medicines; that it improves athletic performance; compares the medicinal product to a foodstuff, a cosmetic, or any other consumer product; may induce erroneous self-diagnosis; refers in an abusive, alarming, or misleading way to claims of recovery; or mentions that the medicine has been granted a public health or any other authorisation, etc. Additionally, there is a prohibition to advertise the following therapeutic indications: tuberculosis; sexually transmitted diseases; other serious infectious diseases; cancer; chronic insomnia; diabetes; and other metabolic illnesses.

Finally, the OTC Guide was approved to clarify and systematise the principles, requirements, limitations and other conditions under which advertising of medicines to the public can be made. Its main objective is to become a basic and essential tool for all that favours the actions of both the pharmaceutical industry (applicant) and the health authorities, harmonising the interpretation of the current regulations in advertising.

### 6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

The advertising of prescription-only medicines to the general public is expressly prohibited in the Law on Guarantees and in Royal Decree 1416/1994.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Health information campaigns fall outside the scope of the laws governing advertising of medicines. Royal Decree 1416/1994 provides, in this regard, that it shall not apply to the information regarding human health or illnesses/diseases insofar as no reference is made, even indirectly, to a medicinal product. Therefore, the broadcast/publishing of health-related information to the public, insofar as such information does not fall within the definition of indirect advertising of a specific medicinal product, should be endorsed. This means that, despite being lawful for pharmaceutical

companies to carry out information campaigns in connection to specific illnesses/diseases, or health in general, in the event such campaigns include any direct or indirect references to a specific treatment or to a medicine, this could be regarded as indirect advertising of a medicinal product and, hence, would be subject to the checks, requirements and prohibitions foreseen in the governing laws of such medicinal product.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Any kind of advertising to the general public related to prescription-only medicines is prohibited. Again, the prohibition would apply if any such press release is construed as advertising, as opposed to information. If the press release is not considered advertising, then such press release may refer to unauthorised medicines or unauthorised indications (please see question 2.3 above).

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

There are no specific requirements applied to describing products and research initiatives as background information in corporate brochures or Annual Reports. We would understand that any such documents would be construed not as promotional materials but as information documents, directed at providing factual information to third parties and shareholders on the performance of the company, so that any mention made should be aimed at informing and not promoting. From a regulatory advertising standpoint, Spanish law requires that any sponsorship activities undertaken by a company must be included in the annual comprehensive advertising index to be submitted to the health authorities, and that pharmaceutical companies keep a record, available to the competent authorities, of the amounts contributed to scientific meetings, as well as a list of the persons qualified to administer, prescribe or dispense medicines-offered hospitality. Reference to any such items may be included in the annual reports. Additionally, Farmaindustria members are required to comply with the transparency obligations mentioned under section 7 below.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

The Farmaindustria Code refers to the principles included in the EFPIA Code of Patient Organisations. In general terms, the collaboration between pharmaceutical companies and patient organisations must comply with the following requirements:

- the independence of patient organisations, in terms of their political judgment, policies and activities, shall be assured;
- all partnerships between patient organisations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value;
- the pharmaceutical industry shall not request, nor shall patient organisations undertake, the promotion of a particular prescription-only medicine;
- the purposes and scope of any partnership shall be transparent. Financial and non-financial support provided by the pharmaceutical industry shall always be clearly acknowledged; and
- the pharmaceutical industry welcomes the broad funding of patient organisations from multiple sources.

Contracting of patient organisations is permitted for providing advisory or consultation services such as communications at meetings as a speaker or moderator, expert meetings, etc. Such service agreements must be formalised in writing and comply with similar requirements to those mentioned under question 5.4 above.

Events directly or indirectly sponsored or organised by a pharmaceutical company must be held at a location that is appropriate in relation to the primary purpose of the event, avoiding sites that are known for their entertainment facilities or those that are extravagant or inappropriate. Hospitality must comply with requirements similar to those mentioned under question 5.1 above. Pharmaceutical companies may only defray or finance these expenses through the patient organisation and never directly to individual patients.

When support provided by the pharmaceutical company to the patient organisation is economic, or of any other type (in kind, etc.), and is significant, a written agreement, and the Farmaindustria Code specifies the terms and conditions of such agreements.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

The Law on Guarantees expressly prohibits premiums, gifts, prizes, contests, bonuses or similar methods linked to the promotion or sale of medicines to the public.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The obligation to disclose details related to clinical trials are imposed both by law and under the Farmaindustria Code. According to Royal Decree 1090/2015 on clinical trials, sponsors are required to disclose the result, either positive or negative, of the clinical trials. Such disclosure should preferably be made in scientific journals before being made to the general public. Additionally, sponsors are required to disclose the report of the clinical trial's results by publishing such report with the Spanish Clinical Trials Registry (REec) (which can be consulted at https://reec.aemps.es). All such disclosure obligations refer to the final results of the clinical trial, to the extent the Royal Decree prohibits the sponsors to disclose interim results which may compromise the reliability of the final results of the clinical trial.

According to the Farmaindustria Code, pharmaceutical companies must provide detailed information on clinical trials in accordance with current legislation and the stipulations of the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2009 and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature 2010", available at http://clinicaltrials.ifpma.org.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no requirement in Spanish legislation for companies to make such information publicly available.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Yes, Farmaindustria members are required to comply with the transparency obligations mentioned under the Farmaindustria Code. The Farmaindustria Code has implemented the transparency provisions of the EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations. The main obligations are as follows:

- document and openly publish on the pharmaceutical company's website, all transfers of value using the template of the Farmaindustria Code. Furthermore, pharmaceutical companies must provide this information to the Surveillance Unit of Farmaindustria annually;
- donations, events (sponsorships, registration fees, travel, and accommodation) and the provision of services, as well as transfers of value relating to research and development; this excludes the delivery of materials, the delivery of samples, and hospitality (lunches or dinners), as well as transfers of value resulting from commercial transactions in relation to non-prescription medicines;
- to the extent legally possible, pharmaceutical companies must publish this information individually, except for transfers of value relating to research and development. If such information is published collectively, the following must be identified for each category: (i) the number of recipients involved; and (ii) the overall amount attributable to these transfers of value. A detailed itemisation must be provided upon request by the recipient and/or the applicable authorities;
- pharmaceutical companies must adopt a specific internal procedure to guarantee compliance with the transparency obligation;
- annual publication within the first six months following each applicable period (calendar year), together with a document summarising the methodology used, the information provided, and how it was obtained and classified. The first applicable period was 2015 and the first publication of data will finish on June 30, 2016; and
- the information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed, unless, in each case: (i) a shorter period is required under applicable national law or regulation; or (ii) the recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked, and this revocation is legally binding for the pharmaceutical company.

All those transparency obligations apply only to those companies which are members of Farmaindustria irrespectively of whether or not they have been granted a marketing authorisation yet. With regard to transfers of value made by foreign companies, the rule is that such transfer must be published according to the Farmaindustria Code if the healthcare professional works in Spain and the company belongs to a group of companies which are members of Farmaindustria, or at least its Spanish subsidiary is a member of Farmaindustria.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

If an individual healthcare professional refuses to agree to the disclosure of a transfer of value, the pharmaceutical company may publish such transfer on a collective basis (see question 7.3 above).

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Internet advertising has not been expressly governed in Spanish medicinal products' legislation. It is commonly accepted as a tangible support for advertising, subject to compliance with all requirements mentioned in the Royal Decree 1416/1994. Accordingly, advertising through the Internet is subject to all controls and requirements mentioned in the Spanish legislation applied to advertising of medicinal products and to the supervision of the health authorities.

According to the OTC Guide, when the advertising of medicines will take place through the Internet, the following requirements must be met:

- the website of the medicine shall only contain information of the medicine based on the prospectus and, where necessary, on the data sheet;
- the upper band of the website may identify the trademark or brand of the medicine if the full name of such medicine appears on the home page;
- the home page shall clearly differentiate information concerning the medicine from other general information; and
- all general information on diseases, tips, etc., will be included as "links" within the home page with the caption "for more information click here" or similar expression related to the content, which will link with other sections in which no information related to the medicine will appear.

Additionally, Royal Decree 870/2013 governing the sale of non-prescription medicines for human use via the Internet has permitted pharmacy offices to sell non-prescription medicines through the Internet (pharmacy offices websites must follow the requirements mentioned under Royal Decree 870/2013) provided they comply with the following requirements: (i) the pharmacy office has made a notification to the authorities of its Autonomous Community (at

least 15 days prior to providing the service); (ii) a pharmacist intervenes in the sale, from the pharmacy officer, providing personal advice; (iii) sales take place directly from the pharmacy office responsible for dispensing the medicine, without the intervention of intermediaries; (iv) no gifts, prizes, presents, contests, discounts or similar may be used to promote sales (notwithstanding the price discounts allowed under current legislation); and (v) sales to patients located in other Member States must comply with Spanish legislation and that of the country of destination, with respect both to medicines (labelling, prospectus and classification), as well as to the conditions of sale. On July 1, 2015, the Spanish Agency approved the website (www.distafarma.aemps.es) which allows pharmacy offices to sell such medicines online. This website includes a list of all the pharmacy offices which may sell OTC medicines through the Internet.

From a self-regulatory standpoint, the Farmaindustria Code has stated that promotional materials for medicines directed to healthcare professionals to be disseminated through the Internet must have a primarily technical/scientific or professional content. The Farmaindustria Code expressly states that in all cases, pharmaceutical companies are responsible for the content disclosed through the media, means of delivery or channels of communication that directly or indirectly control or finance exclusively or in the majority. Therefore, pharmaceutical companies must implement usage and style guidelines that establish rules of conduct, consequences derived from non-compliance, and procedure for monitoring the content to which they provide access, host, temporarily copy or link, as well as guidelines and rules of conduct for their employees that establish standards for responsible conduct in the digital environment.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

The Farmaindustria Code requires measures to be taken to ensure that advertising through the Internet directed at healthcare professionals is only accessible to these professional groups. It must include, in a clearly legible, highlighted manner, a warning stating that the information on the web page is intended exclusively for the healthcare professional authorised to prescribe or dispense medicines; specialised training is therefore required for the correct interpretation of the information. This warning must appear in a clear and prominent way before accessing the information, as well as on the pages, mobile applications or similar outlets in which the information appears. Individuals who access the content must declare their status as a healthcare professional who is authorised to prescribe or dispense medicines.

The Madrid Autonomous Community has approved certain rules on this matter indicating that the existence of an online form to be fulfilled by users in order to gain access to the information which includes mandatory files related to exclusive data of the healthcare professionals could be considered as an effective measure to guarantee that the advertising to a healthcare professional is only accessible to these professional groups.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

With regard to third-party websites that may be accessed by a link from the pharmaceutical company sponsored site, pharmaceutical companies may be held responsible for their contents. According to the Farmaindustria Code in all cases, pharmaceutical companies are responsible for the content disclosed through the media, means of delivery or channels of communication that directly or indirectly control or finance exclusively or in the majority. Therefore, usage and style guidelines must be implemented in a way that establishes a procedure for monitoring the content to which they provide access, host, temporarily copy or link. This procedure must address the obligation to correct any irregularity quickly.

With regard to reverse linking of third-party websites to a pharmaceutical company's website, we understand that the pharmaceutical company should not be directly liable for the content of such websites (to the extent such websites are not directly or indirectly sponsored by the pharmaceutical company nor under the control of such company), although it would be possible that the health authorities request the pharmaceutical company use its best efforts to avoid such linking.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Pharmaceutical companies may place on their websites all information which does not fall within the concept of advertising when referring to prescription-only medicines. With regard to OTC medicines, please see question 8.1 above.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

The OTC Guide approved by the Health Ministry applies the same rules related to the websites to social media. Likewise, the Farmaindustria Code expressly mentions that all its rules related to the digital environment (which mainly refer to the Internet) will also apply to, among others, SMS, MMS, web pages, electronic mail, forums, blogs, social networks, chat, platforms, applications or any other type of digital channel, means of delivery or media.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

There have been no significant developments in the last year.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

In Spain, we are in the process of clarifying if prescription-only medicines may be advertised to nurses. Whether or not it would be possible will depend on whether or not the nurses are able to prescribe certain medicinal products. Royal Decree 954/2015 is currently being amended to clarify the role of the nurses with regard to the prescription of medicines.

Royal Decree 1416/1994 needs to be updated in order to include all developments related to advertising of medicines which have taken place during these past 20 years. In 2018, the process for the approval of a new Royal Decree on advertising of medicinal products commenced. Nevertheless, due to the imminent general elections in Spain, we do not expect such a draft of Royal Decree to be finally approved.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

No, there are no general practice or enforcement trends that have become apparent in Spain.

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# Sweden

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The Medicinal Products Act (SFS 2015:315) provides that all advertising of medicinal products must be up-to-date, factual, balanced, not misleading, and in accordance with good marketing practice. The act contains rules on advertising of medicinal products related to, e.g., prescription or over-the-counter status, targeted audience, and authorisation status. The Swedish Medical Products Agency ("MPA") has issued regulation LVFS 2009:6 on medicinal products to further clarify these rules.

The Market Practices Act (SFS 2008:486) also applies to advertising of medicinal products. The overall rule is that marketing must be compatible with good marketing practice and fair towards consumers and the industry. The act also covers, e.g., issues of misleading and comparative advertising and special offers.

In addition, the Swedish industry code contains detailed rules on pharmaceutical advertising. The Ethical Rules for the Pharmaceutical Industry ("LER Rules") are issued by the Swedish Association of the Pharmaceutical Industry ("LIF") and are regularly revised (most recently on 12 February 2018). Although not legally binding, the LER Rules are recognised by the pharmaceutical industry and healthcare sector alike and are applied by courts as a standard of fair and ethical marketing. Members of the association are contractually bound by the industry code. The LER Rules cover a range of issues, including pre-launch and off-label advertisement, advertising of prescription drugs, comparative advertising, information standards and disguised advertising.

### 1.2 How is "advertising" defined?

The Market Practices Act generally defines marketing (Sw. *marknadsföring*) as "commercial advertising and other business measures intended to promote the disposal of and access to products, including a business proprietor's acts, omissions or other measure or behaviour before, during or after the sale or delivery of products to consumers or other business proprietors".

The Medicinal Products Act does not contain any definition of "advertising" in the context of medicinal products. The legislative bill preceding the Act, however, refers to the definition provided in Directive 2001/83/EC on the community code relating to medicinal products for human use.

The LER Rules moreover apply to any information, regardless of medium, provided by the pharmaceutical industry in connection with marketing operations directed at healthcare professionals or the general public. Also, generally, what constitutes as "advertising" or "marketing" is very broad in Sweden and most information on medicinal products emanating from a pharmaceutical company is considered to be marketing material. Hence, not only do traditional commercials or brochures fall within this definition, but also, e.g., the unsolicited distribution by a pharmaceutical company of a scientific article mentioning a company's products.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no such legal requirements. Under the LER Rules, however, pharmaceutical companies must send new, up-to-date information on medicinal products such as publications, advertisements, invitations, and website information to LIF's Information Examiner Committee (Sw. *Informationsgranskningsnämnden*, "IGN"). On request, the IGN may provide non-binding advance decisions, i.e. general advice on measures before they are implemented.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Under the Medicinal Products Act, the market authorisation holder of a medicinal product must have a specific division in place with scientific competence to supervise the information on the product.

More specifically, pharmaceutical companies are under the LER Rules required to appoint a competent person among the executive staff to be responsible for ensuring compliance with regulatory requirements and for supervising external information and marketing practices. Pharmaceutical companies must also appoint a body to approve and monitor non-interventional studies. These rules apply to drug information aimed at healthcare professionals and at the general public alike.

The appointed person must complete a training course in marketing law arranged by LIF. He/she must approve all marketing material before use, certifying that it complies with applicable laws and regulations, the SmPC, with decisions and recommendations of the

Dental and Pharmaceutical Benefits Agency ("TLV") and that it is a true and unbiased presentation of the facts. The LIF secretariat is to be annually informed of appointed persons and of any changes in responsibilities.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

No, requiring a general pre-approval of this kind by a Swedish authority would be contrary to the Swedish Freedom of the Press Act (SFS 1949:105).

This notwithstanding, the LER Rules provide for a means of granting public access to easily comprehensive information on prescription drugs on demand through websites managed by pharmaceutical companies. Such information may only be provided if pre-approved by the IGN and must, in all parts and on a factual basis, rely on Fass.se (the online version of the FASS catalogue on medicinal products issued by LIF) and on the summary of product characteristics ("SmPC") as approved by the MPA. Furthermore, the pre-approved website must contain patient-appropriate information on the correct administration of the medicinal product in question. Similarly, pre-approval from the IGN on compliance with the LER Rules and other applicable marketing rules is required for vaccination campaigns for humans against infectious diseases.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

As part of its surveillance of the pharmaceutical market, the MPA also monitors the marketing activities of pharmaceutical companies. The MPA primarily seeks voluntary corrections in cases of non-compliance, but if the result is not satisfactory, the MPA may issue a prohibitive injunction subject to fines, or refer the case to LIF's Information Practices Committee (Sw. *Nämnden för Bedömning av Läkemedelsinformation*, "NBL"). The MPA's decisions can be appealed to the Administrative Court. The MPA may also notify the Consumer Ombudsman (Sw. *Konsumentombudsmannen*), who may issue a prohibitive injunction subject to fines upon non-compliance or, depending on the sanctions sought, initiate action under the Market Practices Act in the Patent and Market Court (a part of the Stockholm District Court). Decisions by the Patent and Market Court may be appealed to the Patent and Market Court of Appeal (a part of Svea Court of Appeal). Neither court can assist in issuing a corrective statement.

The vast majority of cases on the advertising of medicinal products are never tried in court, but by one of LIF's two self-regulatory bodies IGN or NBL. The IGN's decisions may be appealed to the NBL, a court-like joint committee. Both bodies may instruct the company to place a corrective statement in a medium of their choosing.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Failing to comply with the rules on advertising under the Medicinal Products Act will normally result in a prohibitive injunction subject to fines. The responsibility for supervision and enforcement lies with the competent authority, i.e. the MPA.

The Market Practices Act provides for several remedies or sanctions depending on the nature of the violation. The rules on, e.g., misleading advertising and special offers are coupled with sanctions of prohibitive injunction subject to fines, market disruption fees of SEK 10,000–10,000,000 and third-party damages. Prohibitive injunctions, by contrast, are the only available remedy when the general clause on unfair marketing is breached. An action on advertising infringement may be brought before the Patent and Market Court by the Consumer Ombudsman or by a private person/company such as a patient, trade/consumer association, or competitor.

Many cases on the advertising of medicinal products are regularly handled by courts, the MPA and other authorities, but also, as the MPA states on its website, a great number of these matters are handled by the two self-regulatory bodies IGN and NBL. The IGN monitors the market and may, without a formal complaint, open or refer a case to the NBL. Private persons and companies (including competitors) may bring actions on advertising transgressions before the IGN. The IGN and the NBL have contractual authority to fine LIF members for violating the LER Rules (a maximum of SEK 500,000 each). Where a violation is gross, the IGN or NBL may, in addition, instruct the pharmaceutical company to make a corrective statement.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The competent authority ("MPA") and the self-regulatory bodies ("IGN" and "NBL") function independently of one another. The MPA may, at its own discretion, choose to take action itself or to notify the NBL in a given matter. The IGN and NBL are also free to try a matter which is, in parallel, investigated by the MPA. All instances may apply the LER Rules, which directly refer to the standard of fair marketing practice.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Unfair competition as a result of unlawful marketing is governed by the Medicinal Products Act, the Market Practices Act and the LER Rules (see questions 1.1–1.8).

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

The main rule is that the advertising of medicinal products that are not authorised for sale in Sweden is prohibited. Equally, it is prohibited to advertise indications or dosages or other variations that are not approved in Sweden. The MPA and the IGN/NBL strictly monitor the market to ensure compliance with these prohibitions.

As an exception to the rule, information on medicinal products that does not qualify as marketing and that is protected by the constitutional right of freedom of speech may be distributed to and discussed with healthcare professionals pre-market authorisation. Information on unauthorised medicines may thus be made available at, e.g., scientific meetings, provided that it does not constitute disguised advertising. Sponsorship of the meeting by the company manufacturing the medicinal product in question will clearly increase the risk of the information being considered as unlawful marketing.

Moreover, information on a medicinal product authorised for sale in other countries may be distributed at international scientific conferences held in Sweden, provided that the majority of the conference participants are from countries other than Sweden. The information must include a notice on the fact that the medicinal product has not been approved in Sweden and mention the countries in which it has obtained market authorisation. Subject to certain conditions, also off-label indications may be presented at such international scientific conferences held in Sweden.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Provided that it is not disguised advertising, information on unauthorised medicines and the off-label use of medicines may be published in scientific journals and in articles written by independent journalists.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Press releases about medicinal products have, in Swedish case law, been regarded as unlawful marketing based on the purpose of the information, linkage to an upcoming authorisation and the availability of the information. In 2013, the Administrative Court of Appeal upheld the lower instance's judgment which altered the (until then) longstanding view that press releases aimed at journalists and news editors do not constitute marketing and are protected by the constitutional right of freedom of speech. Instead, the Administrative Court applied a wide definition of marketing, held that journalists belong to the general public and found that a press release about a prescription medicine constituted unlawful marketing. The court also considered it relevant that information published, e.g., online is technically available to anyone, even if it must be actively sought and cannot be obtained by accident.

In a more recent case, the NBL did not consider a press release regarding clinical trial results to constitute marketing (and thus not constitute prohibited marketing of an unauthorised medicinal product), concluding that an assessment must be made of the overall content and purpose of the press release.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Information on an unauthorised medicine or indication may be sent to a healthcare professional only in response to her/his specific request and to the extent required to meet the request. Any other dispatch of such information to healthcare professionals will normally be regarded as unlawful pre-launch marketing.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

We are not aware of any legislative or regulatory changes following the *Ludwigs* case.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

No, sending such information to institutions would likely be considered unlawful pre-launch marketing by the MPA.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The LER Rules generally only allow for a limited scope of market research activities aimed at healthcare professionals by pharmaceutical companies regarding medicinal products. Market research may, among other things, only consist of interviews, focus groups or questionnaires, and any remuneration must be proportionate to the time invested and the activity must not be designed to influence respondents or to convey sales contacts, but to gather opinions or information.

Although market research exercises regarding medicinal products which are yet to be authorised or indications are not *per se* prohibited, the notion of "conveying sales contacts" has in practice been interpreted broadly by the IGN/NBL. Describing a medicinal

product in favourable terms to healthcare professionals would, for instance, be considered to be paving the way for an upcoming launch and thus as conveying sales contacts. This holds true even if neither the brand name nor the generic name is mentioned. It is also important that the design of the market research exercise is functional and reasonable with respect to its stated purpose. Any market research exercise covering unauthorised drugs or indications would thus have to be very carefully designed in order not to violate the general prohibition on promoting unauthorised medicines and indications.

## 3 Advertisements to Healthcare Professionals

### 3.1 What information must appear in advertisements directed to healthcare professionals?

If the text in the FASS catalogue or the SmPC is not copied directly, an advertisement for a medicinal product sent to a healthcare professional must include at least the below information:

- the name of the medicinal product;
- the pharmaceutical form and, if required, the strength;
- the names of active ingredients, stated by generic name next to the brand name when first mentioned in a heading or if otherwise highlighted;
- a balanced statement on the product characteristics, including a pharmaceutical group or other accepted group and indication/area of indications;
- sufficient warnings or limitations regarding the use of the medicinal product;
- the name and contact details of the company responsible for marketing the medicinal product or of its authorised representative;
- the date of publication (or last update, if published online);
- the date of the last SmPC revision;
- whether the medicinal product is an over-the-counter or prescription product;
- whether the medicinal product is subsidised by the Swedish benefits scheme and if so, the price per subsidised package and any limitations in the subsidy decision); and
- a reference to Fass.se.

The information must always be correct, up-to-date, verifiable and detailed enough for the recipient to be able to assess the medicinal product's value as a treatment. If the advertisement contains quotes, numerical data or diagrams from a scientific study or compares medicines based on such a study, reference must be made to the source.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

The information that may be presented in an advertisement is strictly governed by the LER Rules and, by extension, the marketing legislation. Information on medicines must always be correct and may not be intended to mislead in any way. The LER Rules additionally provide, among many other things, that statements on the quality and efficacy of a medicinal product must be verifiable, any claim supported by qualitative scientific sources, and that drugs may never be claimed to be free from side effects or risk for toxicity, abuse or addiction.

The question of the extent to which drug information may contain references to scientific studies or experiences that have not served as the basis of the drug's SmPC is in fact one of most common issues brought before LIF's self-regulatory bodies. Upon request, the NBL therefore issued an advisory opinion in 2014, stating that although the starting point is that the SmPC must be the factual basis of any drug information, there is a limited scope for relying on new evidence and experience from qualitative scientific studies. However, such new findings must still fall within the scope of the SmPC, i.e. must in practice confirm and clarify the information in the SmPC, and may not concern essential information such as time to effect, new indications or new dosages. Moreover, the NBL stressed that this assessment must be made on a case-by-case basis and that the outcome will vary depending on whether the information is directed at healthcare professionals or the general public, among other things.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Yes. The LER Rules prohibit pharmaceutical companies from having healthcare professionals contribute to the drug information act as a guarantor for a particular product or recommend a certain treatment. Correspondingly, the Swedish Medical Association (Sw. *Sveriges läkarförbund*), a union in which the majority of Swedish medical doctors are members, has issued rules on advertising healthcare services which prevent its members from contributing to drug information aimed at the general public and to promotional material as guarantors for a particular medical product or a product developed by a third party which is associated with healthcare services.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There is no such general requirement, but information on the quality and efficacy of a medicinal product must always be verifiable through qualitative scientific sources.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

The Medicinal Products Act does not cover the issue of comparative advertisements, but the Market Practices Act contains some general provisions. Among other things, a comparison may not discredit or denigrate a competitor or take unfair advantage of the reputation of a competitor's trademark, trade name or other distinguishing symbol.

Moreover, the LER Rules provide detailed guidance in this regard. Hence, comparisons relating to efficiency, ingredients and treatment costs in drug information must give a fair overall picture of the compared products. The objects of comparison must be relevant, selected fairly and presented in an objective and factual manner. A fair comparison requires, among other things, that:

- the objects of comparison always be clearly identified;
- the facts to be clarified by the comparison, and the limitations of this comparison, be clearly presented;

- the comparison of properties between synonymous drugs or drugs with the same indications provide a comprehensive and fair picture of the compared properties; and
- the presentation may not induce incorrect or misleading conclusions regarding properties that are not covered by the comparison.

Further, comparisons between drugs or groups of drugs may not be included on pre-approved websites. If necessary for the sake of clarity, the complete name and generic designation of the compared drugs must be stated (though it should be noted that the use of another company's trademark could constitute trademark infringement).

As regards the issue of referring to a competitor's unauthorised medicinal product or indication, such reference would be included in the general prohibition and hence not be permissible in the marketing context (see question 2.1).

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The (unsolicited) distribution of scientific papers or similar material regarding the company's own products will likely be considered as marketing when addressed to a healthcare professional, even if the material *per se* is of non-promotional nature. The rules on the advertising of medicinal products, as set out in this chapter, thus apply.

### 3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

A "teaser" advertisement of this kind would risk being viewed as unlawful pre-launch marketing even if the name of the product is not stated, especially if the advertisement is part of other information activities drawing attention to the new product.

### 3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

The Medicinal Products Act and the LER rules prohibit marketing of unauthorised medicinal products, which includes promotion of an unauthorised indication, i.e. promotion of off-label use.

The LER rules provide that the SmPC that has been adopted for a medicinal product constitutes the factual basis for information on the medicinal product. Promotion by the MA holder for Product A concerning use of Product A in combination with Product B would thus not entail promotion of an unauthorised indication or medicinal product, as long as the information is solely based on the SmPC for Product A. It is not permitted to add any other information on, e.g., Product B other than what is explicitly set out in the SmPC for Product A about the combination use.

The MA holder for Product B would not be permitted to rely on Product A's SmPC since medicinal product information may not contain any other indications or dosages than those authorised for the medicinal product in question.

## 4 Gifts and Financial Incentives

### 4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Under the MPA regulation on the marketing of medicinal products for human use (LVFS 2009:6), free samples of medicinal products authorised for sale in Sweden may be provided to persons qualified to prescribe the product, licensed open-care pharmacies, managers of open-care pharmacies and designated pharmacists at hospital pharmacies. The promotional supply of samples of medicinal products to any other recipient is explicitly prohibited.

In addition, medicinal product samples may only be supplied in a very restrictive manner and if the following conditions are met:

- only a limited number of samples of each medicinal product is provided to the same recipient per year;
- each sample delivery is preceded by a written, dated and signed request by the recipient;
- it has been thoroughly investigated that the recipient is qualified to prescribe or expedite the medicinal product in question (and orders are kept and filed);
- no sample is greater than the smallest available package size;
- each sample is labelled with "free medicinal product sample, not for sale" or similar; and
- each sample is accompanied by a copy of the product's SmPC.

No samples may be used in the treatment of humans. The distribution of samples of medicinal products categorised as narcotics by the MPA is not allowed.

Under the LER Rules, maximally one sample per year may be provided to one and the same person. Samples of prescription drugs may only be provided of new drugs that have been publicly available for up to two years (and a new strength or new pharmaceutical form is not considered a new product). Lastly, drug samples may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Giving gifts or donations of money to healthcare professionals is generally prohibited. The Criminal Code (SFS 1962:700) stipulates that a person who provides, promises or offers an improper benefit to an employee for carrying out her/his service may be held responsible for bribery. The same holds true for an employee who for this purpose receives, accepts a promise of or requests an improper benefit.

The LER Rules allow gifts to healthcare professionals in the following circumstances:

- information and educational material of low value that is of direct relevance to the recipient's professional practice and of direct benefit to patient care; or
- items of medical utility for the purpose of educating employees and to enhance patient care, if of low value and not routinely used in the recipient's practice.

None of the above may be supplied, offered or promised to healthcare professionals as an incentive to recommend, prescribe, purchase, supply, sell or administer medicinal products. The threshold for "low value" was set to SEK 450 in an LIF board decision.

It is important to note that adherence to the LER Rules and the monetary threshold for gifts does not exclude criminal liability. There may be situations where the provision of a gift worth less than SEK 450 is considered bribery.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

As a main rule, the prohibition of gifts and donations of money also apply to legal entities within the healthcare sector (*cf.* question 4.2 above).

The LER Rules also provide for a limited scope of making donations to the healthcare sector if made for the purpose of supporting research and development and if, in addition, the following requirements are fulfilled:

- the donation is made in a transparent and well-documented manner;
- the donor keeps a register of received donations;
- the donation is not linked to any prior, current or future use, recommendation, sale or prescription of the donor's products or services;
- the donation does not constitute an incentive to recommend, prescribe, buy, offer, sell or administer specific medicinal products; and
- the donation is not in any way offered or requested for the funding of internal or routine operations or recreational activities of the healthcare organisation.

To a certain extent, LER Rules allow for a pharmaceutical company to bear certain costs for, e.g., medical or technical services, if these are part of a joint project between the company and a healthcare entity. Among other things, the institution/clinic is required to also contribute with resources to the project and the overall purpose of the project must be to benefit patients. The set-up and boundaries of such projects are also subject to detailed rules on, e.g., establishing agreements and project documentation.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The limited scope for providing information and educational material and items of medical utility to healthcare professionals is explicitly prohibited if used as an incentive to recommend, prescribe, purchase, supply, sell or administer medicinal products (*cf.* question 4.2 above). Providing medicinal or educational goods and services intended to affect prescription patterns would therefore be very likely to be considered unethical and unlawful.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

The Swedish rules on advertising and inducements do not prohibit offering volume-related discounts to healthcare institutions, but such arrangements could have competition law implications depending on the circumstances.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

The scope for providing medical or technical services or equipment to the healthcare sector is very limited *per se* (see question 4.2 above). Package deals are not prohibited, but when a product or service is provided as a "benefit" contingent on the purchase of medicinal products, rather than paid for by the recipient, it is likely to be considered an improper benefit. Such an arrangement could also have competition law implications.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

All companies are under the Sales of Goods Act (1990:931) required to refund customers for sold products that do not fulfil the necessary requirements. In the case of medicinal products, however, refund schemes or money-back guarantees must also adhere to good marketing practice under LER and the Medicinal Products Act. Returns of prescription-only medicines from open care pharmacies is, as of 1 August 2018, regulated by the Act (2009:366) on Trade with Medicinal Products. Said act stipulates, e.g., that a wholesaler is obligated to provide for returning a product under some of the circumstances and to credit the pharmacy at the purchase price.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Financial support to the healthcare sector is a sensitive issue and great care must be taken to not challenge the integrity and independence of the medical profession. The Swedish Association of County Councils has enforced a statement in the preamble of the LER Rules which highlights that it is the employer's responsibility to ensure and finance the continuing education and professional training of healthcare professionals. Accordingly, the options for pharmaceuticals to sponsor and/or co-host educational events are mainly limited to two forms of sponsorship/co-organisation of healthcare events as governed in detail by the LER Rules.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

The Criminal Code stipulates that a person who provides, promises or offers an improper benefit to a recipient for carrying out her/his service may be held responsible for active bribery. The receiving person may be held responsible for passive bribery. The rules apply both within the public and private sector and the acceptance level regarding benefits is very low in Sweden. Great care must therefore always be taken when offering any hospitality to public or private healthcare professionals.

In addition to active and passive bribery, the act of negligent financing of bribery (Sw. *vårdslös finansiering av mutbrott*) criminalises the provision of money or assets by a senior person of a company to another person representing the company in a certain matter, and thereby through gross negligence abets an act of bribery.

Criminal cases regarding bribery are handled in ordinary courts.

The MPA is formally responsible for supervising and enforcing the rules on pharmaceutical advertising and may issue prohibitive injunctions subject to fines in case of violations of the Medicinal Products Act. In addition, matters of advertising infringement under the Market Practices Act may result in prohibitive injunctions subject to fines, market disruption fees and third-party damages by the Patent and Market Court.

In practice, most cases of both pharmaceutical advertising and anti-corruption are primarily subject to the LER Rules and their enforcement through LIF's self-regulatory bodies. Under these rules, the basic principles of mutual benefit and patient need, transparency, proportionality, moderation and documentation must govern all interactions between pharmaceutical companies and healthcare professionals. A very common matter combining aspects of anti-bribery and advertising and which is subject to enforcement through the self-regulatory bodies and LIF's Compliance Officer, is, for example, the choice of venue for a scientific meeting or event. The fact that a case is tried by LIF's self-regulatory bodies does not exclude criminal liability.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Acts of undue hospitality may be considered bribery under the Criminal Code and any deliberated offering of hospitality should therefore first be reviewed for compliance with the regulatory framework, as described in detail under question 4.9 above. The criminalised act must be connected to Sweden in order for Swedish courts to have jurisdiction and for Swedish law to apply. This will be the case if any part of the criminal act was committed in Sweden (e.g. if the hospitality is paid by a Swedish entity) or, if it is uncertain where the criminal act was committed, there is reason to believe that it was committed in Sweden. If the crime was wholly or partly committed abroad, Swedish courts have jurisdiction and Swedish law is applicable if the person who committed the crime in some way is connected to Sweden either by citizenship, domicile or if he or she is present in Sweden. Thus, hospitality offered to healthcare professionals abroad may be subject to the Swedish bribery regulation.

Under the LER Rules, the possibility of offering hospitality abroad is limited. Companies may not arrange or provide financial support for arrangements held abroad unless the majority of those invited come from other countries than Sweden or the corresponding knowledge or experience cannot be found in Sweden. The choice of location and venue of a meeting must always be reasonable in relation to the purpose of the meeting and locations known for their exclusivity or leisure activities, such as ski resorts, should be avoided. The same applies to locations at which, e.g., major international sports events are being staged around the same time as the meeting, and companies may also not contribute financially to meetings held at such locations. Members of LIF can ask LIF's Compliance Officer to determine if a location can be deemed acceptable. The Compliance Officer's decision in this respect can be appealed to the NBL.

There are no specific rules on which a company affiliate is to approve such hospitality or meals. However, since it is the hospital or institution affiliation of the healthcare professional that determines whether Swedish or foreign rules will apply to a company's interactions with that person, the company affiliate with the most knowledge of the local rules should be the one to approve the hospitality offer at hand. This also aligns with the transparency rules, which provide that disclosures of transfers of value are to be made in accordance with the national code of the country where the recipient has its principal seat. If the recipient instead has its principal seat in another European country, and the company cannot make disclosures through an affiliate in the country of the recipient, the company is to do so in accordance with the LER Rules.

LIF has issued thresholds for meals and hospitality provided to healthcare professionals. The value of a lunch or dinner may not exceed SEK 250 and SEK 700 (including VAT) per person, respectively. Local rules take precedence regarding hospitality abroad, but in the absence of such rules, the Swedish levels apply.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Pharmaceutical companies may generally pay for the venue, speakers, study materials, relevant meals, etc. as necessary to carry out the scientific meeting. The hosting or sponsorship of such meetings is subject to rather restrictive rules that vary depending on whether the meeting is organised by the company or by healthcare.

In both instances, it is prohibited for the company to pay for, e.g., enrolment fees, travel expenses and accommodation for healthcare professionals. Companies also may never arrange or pay for

unrelated side arrangements for a scientific meeting. Social activities and entertainment, e.g., theatre or golf, may not be offered regardless of whether the meeting is held in Sweden or abroad. The duration of the stay must not exceed the time necessary to fulfil its purpose and the company may not pay the participant for her/his time or offer any other kind of reward for her/his participation. Guests or relatives of the healthcare professional may not be invited or paid for.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Please revert to questions 5.1 and 5.2 above. In addition to monitoring the advertising of medicinal products (as outlined under question 1.7 above), the IGM, the NBL and LIF's Compliance Officer also supervise and open cases on companies suspected of breaching the rules of interaction with healthcare professionals and organisations. Patient organisations, private individuals (including other healthcare professionals) and other companies may also initiate such investigations through formal complaints. LIF members may be fined up to SEK 500,000 in total by the IGN and the NBL.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

The Swedish regulatory framework allows for engaging healthcare professionals as speakers at scientific meetings, participants in advisory boards, for research or for other expert services. Specific requirements that must be met under the LER Rules include the conclusion of written agreements between the healthcare professional, her/his employer, and the company. Moreover, any compensation of relevant travel and accommodation expenses must be in line with the employer's own policy on such reimbursement. A healthcare professional may be engaged in an advisory board only if she/he can contribute with expertise in a particular area where such expertise cannot be found within the company. She/he may be paid a reasonable hourly honoraria or fee corresponding to the time and effort invested into the assignment.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

The conduct of post-marketing surveillance studies is governed by the Medicinal Products Act, the MPA Regulation LVFS 2012:14 and the LER Rules and it is permitted to engage healthcare professionals to take part in such phase IV studies. The requirements largely correspond to those relating to advisory board participation and other expert services, as outlined under question 5.4.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Within the boundaries set out under question 2.7 above, healthcare professionals may be engaged in market research activities such as completing questionnaires or surveys relating to medicinal products and treatments. It follows from the prohibition on using market research to convey sales contacts that such material may not be of promotional nature. Any remuneration must be reasonable and correspond to the time and effort invested, and may in any event not exceed 2.5% of the current base amount (Sw. *prisbasbelopp*), corresponding to SEK 1,163 in 2019.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Advertising non-prescription medicines to the general public is permitted (except to children) under the legislation outlined under question 1.1 above and under the LER Rules on information and advertising aimed at the general public.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

As detailed under sections 1 and 2 above, advertising prescription-only medicines to the general public is explicitly prohibited under the Medicinal Products Act and the LER Rules. Exceptions to this rule are, to a varying extent and under the conditions outlined above, vaccination campaigns against infectious diseases, information on websites from Fass.se and providing patient aids via healthcare professionals.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Established case law from the NBL provides that a distinction is made between three types of information: non-commercial medical information (protected by the right of freedom of speech); product information (governed by applicable marketing legislation); and educational information (viewed as a mixture of the two). Educational information does not constitute advertising, but since the NBL recognises that a pharmaceutical company may nonetheless have a commercial interest in initiating, e.g., disease awareness campaigns, it feels at liberty to apply relevant parts of the LER Rules by analogy to such campaigns. Disease awareness campaigns are thus permitted, but must comply with the general LER requirements of objectivity, representing a fair and trustworthy presentation of information, etc. and must also focus on the disease and not on available treatments in order not to risk being considered a disguised prescription drug advertisement.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Please see question 2.3 above.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

General descriptions of products and research initiatives in corporate brochures and Annual Reports is generally permitted. As such information is addressed to investors, shareholders, etc. the rules on advertising of medicinal products are not applicable.

Nonetheless, corporate brochures in and of themselves generally constitute marketing material. Care should therefore be taken in the selection of routes of distribution and targeted audience (i.e. potential investors only or the general public), as well as in the language used and the level of detail in product and research descriptions, in order for the brochure not to be considered as drug advertising and, as such, become subject to the prohibitions on advertising unauthorised medicines, prescription drugs, etc. to the general public.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Interactions with and support of patient organisations are subject to a specific chapter in the LER Rules. All types of user organisations, including patient organisations, disability organisations, senior citizen associations and organisations for relatives, are encompassed. Among other things, agreements between pharmaceutical companies and organisations must be concluded in writing and be made available to third parties, financial support may only be given for certain projects and activities, all cooperation must be conducted in a way that upholds the parties' independence in relation to each other, and the parties' cooperation must always be evident in information materials.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Pharmaceutical companies may not provide any items directly to patients, and the possibilities to provide items for the benefit of patients are very limited. As described under question 4.2, an item may be provided to healthcare organisations, professionals or pharmacies for the benefit of patients only to the extent that it qualifies as a low value educational material or item of medical utility.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The LER Rules require companies to comply with the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" of 10 November 2009 concluded between the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), the Japanese Pharmaceutical Manufacturers Association, the International Federation of Pharmaceutical Manufacturers and Associations, and the Pharmaceutical Research and Manufacturers of America. Thus, all ongoing and completed clinical trials must be registered in a publicly available database such as WHO's clinical trial portal (http://apps.who.int/trialsearch/) and should include at least the following information: brief title; clinical trial description; phase, status and purpose; intervention type; condition or disease; key eligibility criteria including gender and age; location of the trial; and contact information. As regards the publication of clinical trial results, the LER Rules require companies to comply with the corresponding "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature" of 10 June 2010.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

No, there is no specific legislation in this regard.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Yes. The LER Rules directly ratify the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and apply to all companies within the pharmaceutical sector that target or are active in the Swedish market. Both foreign companies and companies awaiting a market authorisation may thus well be comprised, depending on the circumstances.

A "transfer of value" is defined as any direct or indirect transfer or value, in cash or in kind, in connection with the development or sale of medicinal products for human use irrespective of whether for promotional purposes. Direct transfers of value are those made directly by a pharmaceutical company to or for the benefit of a recipient. Indirect transfers of value are those made on behalf of a pharmaceutical company by a third party (e.g. a subcontractor, a cooperation partner or affiliate) to or for the benefit of a recipient, provided that the company knows or can identify the recipient.

Transfers of value made during each calendar year must be disclosed annually in Swedish (and preferably also in English) in the form provided in Appendix 1 of the LER Rules in a designated section of LIF's online cooperation database or on the company's own website. The types of transfers to be disclosed are sponsorships, donations, financial support of meetings and remuneration for consultations and assignments. As a rule, the transfers of value made per year must be disclosed on an individual basis for each identifiable recipient where reasonably allocable to one of the above categories. They may be aggregated by category if the itemised disclosure is upon request made available to the recipient or concerned authorities.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

It follows from the disclosure form in Appendix 1 of the LER Rules that the disclosure of transfers of value made to individual healthcare professionals is to include that individual's full name. Since this constitutes processing of the healthcare professional's personal data, it is necessary that her/his explicit, voluntary consent to the disclosure of the transfer(s) of value in question is obtained prior to disclosure. The issue is, in practice, often settled as part of the agreement(s) governing the parties' cooperation, but the company may not in any way pressure the healthcare professional to consent to the disclosure if she/he does not wish to do so.

Since it is the company that is bound by the transparency rules and since these rules are obligatory, companies should refrain from making transfers of value to healthcare professionals who do not accept the disclosure of such transfers.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Internet advertising of medicinal products is subject to the same rules as advertising in any other Swedish media, i.e. primarily to the Medicinal Products Act, the Market Practices Act and the LER Rules. The NBL has taken the view that a website falls within its jurisdiction if the site is aimed at the Swedish market (under the country of destination principle) and the self-regulatory bodies are rather efficient in their supervision of websites. Please see question 1.5 regarding website information on prescription drugs.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Long-standing case law from the NBL/IGN provides that no particular website security is required, provided that it is clearly stated on the website that it is aimed at healthcare professionals and not at the general public. A common solution is to ask visitors entering the website to answer whether they are healthcare professionals, and to thereafter present different information on the site depending on the answer.

It may, in this context, be of relevance that the court case of 2015 mentioned under question 2.3 highlighted the fact that there are no technical barriers against anyone accessing a press release. This implies that some website security measures would be required to ensure that information cannot be deemed to be aimed at the general public. Although this goes against all previous case law from the IGN/NBL and we are not aware of any legislative or regulatory changes at this point, this case may indicate an upcoming shift towards higher website security requirements.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Information that may be accessed by link from a company-sponsored website implies responsibility for the linking company in respect of the accuracy of said information. A company will, however, not be liable for any reversed linking undertaken independently by another party.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Pharmaceutical companies may publish information on prescription medicines aimed at the general public only by way of linking to Fass.se (see question 1.5 above).

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

Aside from the LER Rules, which apply also to social media, LIF has issued special guidelines on compliance with the LER Rules in the use of social media.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

The rules on pharmaceutical advertising, and particularly the LER Rules, are subject to frequent and regular revisions and amendments. The trend is towards stricter rules, particularly in matters relating to hospitality and bribery/anti-corruption. Another trend is to require more information about the medicinal product and possible adverse events in advertisement.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

We are not aware of any particular developments to be expected in the next year.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

Aside from the general trend towards stricter rules and enforcement of the rules on advertising medicinal products as mentioned under question 9.1 above, we note that the most common cases brought before the IGN in the past year concerned content and form of medicinal product information and comparisons made between medicinal products or alternative treatments.

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Mannheimer Swartling is the leading business law firm in the Nordic region. The firm works with many of Sweden's and the world's leading companies.

Our Life Sciences team advises in all areas, from R&D and clinical trials to market access and distribution of the final product. Our clients include multinational corporations as well as start-ups and other entrepreneurial ventures in the pharmaceutical, biotechnology and medical device industries. We also advise in matters relating to foods, supplements and borderline products as well as cosmetics.

We regularly advise clients in matters before the Pharmaceutical Industry's self-regulatory bodies IGN and NBL, the Medical Products Agency, other authorities and administrative and civil courts. We also act for companies in all aspects relating to proposed legislation in the pharmaceutical industry, including the current review of pricing and reimbursement of original drugs.

Mannheimer Swartling provides a full range of transaction and advisory services, and the Life Sciences group regularly cooperates with other practice groups within the firm, such as Intellectual Property, EU Competition Law, Corporate Commercial and Mergers & Acquisitions.

# Switzerland

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, hereinafter "**TPA**", https://www.admin.ch/opc/en/classified-compilation/20002716/index.html) is the main statute regulating advertising of medicinal products and medical devices. The TPA sets forth the requirements for the manufacture, marketing authorisation, wholesale, distribution, dispensing and advertising of medicinal products. The Federal Ordinance on the Advertisement of Medicinal Products also provides for rules on advertising of medicinal products (hereinafter "**AWV**", https://www.admin.ch/opc/de/classified-compilation/20011778/index.html, no translation in English available).

Moreover, there are several guidelines enacted by Swissmedic, the agency responsible for the authorisation and supervision of therapeutic products, ruling specific forms of advertising of medicinal products and published in the Swissmedic Journal (www.swissmedic.ch).

Among the guidelines on the interaction between industry and healthcare professionals (hereinafter "**HCPs**") enacted by the industry, the Pharma Code and the Pharma Cooperation Code by Sciences industries (https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code) based on private law and binding the vast majority of pharmaceutical companies operating in Switzerland, shall be mentioned.

### 1.2 How is "advertising" defined?

The advertising of medicinal products is defined as all measures of information and promotional purposes, for cultivating marketing and for creating incentives with the goal of promoting additional dispensing, sales, consumption or use of medicinal products (article 2(a) AWV). Advertising includes both advertising to HCPs and advertising to the general public, as well as the offers of material benefits to professionals.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The marketing authorisation holder is required to elect a person who is responsible for the advertising of the medicinal products it distributes in Switzerland (article 25 AWV). He or she must ensure that the advertising materials are compliant with the statutory regulations, keep a copy of such materials for six months after their last publication, and hold a register with the names of all addressees, the details of the publications and the date of the first publication. The person responsible for advertising has to ensure the enforcement of Swissmedic's requests and for providing to Swissmedic all requested materials.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

As mentioned under question 1.3 above, the marketing authorisation holder by law has to elect a person who is responsible for compliance of the advertising of the medicinal products. This person must have a scientific, medical or similar formation or experience. In addition, the Pharma Code requests pharmaceutical companies set up a scientific service which is responsible for information about their medicinal products and for ensuring the conformity of all promotional and informational materials with the Pharma Code and applicable laws (rule 53 Pharma Code). Despite this, no specific SOPs have been enacted yet.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Any advertising to the general public – regardless of the medium used (aired on radio, TV or cinemas, or published in printed or electronic media) – for preparations of the so-called sensitive groups

(analgesics, sleep-inducing products, sedatives, laxatives and anorexics) with a potential for dependence or abuse mentioned in the medicinal product information must be submitted to Swissmedic for prior written approval (article 15(a) and (c) and 23(1) AWV, *cf.* Swissmedic Journal 8/2016, p. 644 *et seqq.*). The procedure for approval is divided into two stages. First, the intended project is assessed based on a script or storyboard and approved or rejected by a preliminary decision. In a second stage, the final advertising product must be submitted to Swissmedic for final approval.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Swissmedic has the authority to enforce the TPA and the AWV through different administrative measures (article 66 TPA). It may seize, hold in official storage, destroy or prohibit the use of illegal advertising media, and publish the prohibition at the expense of the responsible parties. Moreover, it may temporarily or permanently stop the advertising of a specific medicinal product in the event of serious or repeated infringements of the TPA and AWV provisions, and publish the prohibition at the expense of the responsible parties (article 66(2)(f) and (g) TPA). Generally, Swissmedic may inform the general public about medicinal products that endanger health, in particular regarding authorisation and revocation decisions as well as about amendments to professional and patient information (article 67(1) TPA). Administrative measures ordered by Swissmedic can be appealed with the Federal Administrative Court or the Swiss Supreme Court.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Any person who contravenes the regulation on the advertising of medicinal products shall be liable to a fine of up to CHF 50,000 (article 87(1)(b) TPA and article 333(3) of the Swiss Criminal Code, hereinafter "**SCC**", https://www.admin.ch/opc/en/classified-compilation/19370083/index.html). If that person acts in a professional capacity, the penalty shall be a custodial sentence of up to three years or a monetary penalty (article 87(2) TPA and article 333(2) and (5) SCC).

Swissmedic may criminally prosecute cases against persons and companies violating the TPA, insofar as the prosecution is conducted at federal level. If the prosecution is conducted at cantonal level, e.g. when the non-compliant advertising is displayed at a professional congress only, the penal cantonal authorities are responsible (article 90 TPA).

The rules are strictly enforced. An important and contentious example was the prosecution of Pfizer for the distribution of a brochure on migraines and their medical treatment, in which Swissmedic recognised a non-permitted promotion of the medicinal product Relpax (decision of the Swiss Supreme Court 2A.63/2006).

The TPA does not provide rules for civil claims. Therefore, competitors have to base civil claims on alternative statutory provisions to file an action with a court such as potentially under tort law or the Federal Act against Unfair Competition (Unfair Competition Act, hereinafter "**UCA**", https://www.admin.ch/opc/de/classified-compilation/19860391/index.html#a3, no translation in English available).

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

Swissmedic is very active in marketing surveillance and does not tolerate the infringement of advertising statutory provisions. Accordingly, competitors often contact Swissmedic and require its intervention when they become aware of the infringement of advertising provisions. Swissmedic may also take up matters based on an adverse finding of a self-regulatory body. Often used as a first choice by competitors is, however, also the filing of a complaint with the Pharma Code Secretariat (self-regulatory body), which is responsible for the implementation of the Pharma Code and also indirectly verifies the compliance of advertising with TPA and AWV regulations. By choosing the Pharma Code Secretariat, pharmaceutical companies avoid being exposed to penal administrative proceedings, which may be effort- and time-consuming.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Any incorrect or misleading statements about its own products (article 3(1)(b) UCA) or about the products of competitors (article 3(1)(a) UCA), as well as any measures that may cause confusion with competitors' products or business (article 3(1)(d) UCA), can be challenged in civil or penal unfair competition proceedings by competitors. Cantonal courts have exclusive jurisdiction and their decisions can be appealed with the Swiss Supreme Court. Within civil proceedings, provisional measures may be obtained quickly and decisions may be enforceable in other countries.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Scientific information can be made available to HCPs before the medicinal product has obtained marketing authorisation under specific circumstances, e.g. at scientific meetings, but advertising of such medicinal products remains strictly prohibited (article 32(1)(c) TPA). In any case, it must always be clearly stated that the medicine

is not yet authorised by Swissmedic (rule 242 Pharma Code). The same rules basically apply to off-label information. Advertisements for off-label use of a medicine are unlawful (article 5(1) AWV), but not information on off-label use of a medicinal product, namely in scientific articles or congress reports.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Such information may be published as long as it does not qualify as an advertisement (e.g. scientific articles).

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Pharmaceutical companies may issue press releases about unauthorised medicines and off-label information. It is legal to use the brand name; however, the International Nonproprietary Name ("**INN**") of the compound has to be used as well. Nevertheless, companies should make sure that press releases are not interpreted as unlawful advertising acts (rule 241 Pharma Code). For this, press releases should not be published in mainstream public media but only in specialised medical or scientific media.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

It is permitted for pharmaceutical companies to send off-label information to HCPs. They may also inform HCPs about new indications, possible applications, dosages, pharmaceutical forms and packing of medicinal products (rule 241 Pharma Code). In any event, it must always be clearly stated that this medicinal product has not yet received marketing authorisation from Swissmedic (rule 242 Pharma Code).

It is not required that a single HCP requests information. However, it is unlawful to send unrequested mass mailing to HCPs (article 3(1)(o) UCA).

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The *Ludwigs* case has not yet been reflected in the Swiss legislation or in practical guidance in Switzerland. Independently of the above judgment, since 2002, the AWV states in article 1(2)(b) that its rules on advertisement do not apply to price lists. As a consequence, it is likely that the availability of price lists for non-approved medicinal products to pharmacists are not to be considered non-permitted off-label advertisements.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Considering that most medicinal products are listed for reimbursement by healthcare insurers and that the prices for such products are determined by regulatory authorities only after the new medical indications are approved and immediately before the products are distributed on the Swiss market, there is no reason for a pharmaceutical company to disclose information on unauthorised medicines just for budget proposals. Under these circumstances, it is likely that such information would qualify as an unlawful advertisement.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

In principle, it is not prohibited for pharmaceutical companies to engage with HCPs for consultancy services (rule 211 Pharma Cooperation Code). Essentially, HCPs' involvement needs to be transparently disclosed by the pharmaceutical company. As market research is conducted with the purpose of advertising off-label indications to HCPs only (e.g. for non-scientific publications), engagement with HCPs is to be considered an unlawful advertising measure.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Any advertisement to HCPs must be recognised as such and editorial contributions must be clearly separated from advertisements (article 5(4) AWV). The content of the advertisement must comply with the product information approved by Swissmedic, in particular with regard to the indications and contraindications (article 5(1) AWV). In order to be comprehensive, the following information must be contained in advertisements: (i) drug name (brand); (ii) INN of the compound; (iii) name and address of the marketing authorisation holder; (iv) at least one indication or use of the medicine, as well as the dosage and the method of application; (v) a summary of the restricted use, contraindications and interactions; (vi) the distribution category; and (vii) the mention that further information can be found in the product or patient information (article 6 AWV).

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

Advertisement is limited to the authorised indications and use of the medicine (article 5(1) AWV). In addition, the advertisement must not be misleading, incite abusive, excessive or inappropriate use of medicinal products, or be contrary to public morality and order (article 32(1) TPA). Moreover, statements must be accurate,

truthful, well-balanced, provable by up-to-date scientific findings, and must not be misleading. All statements in the advertisement have to comply with the medicinal product information authorised by Swissmedic (which in Switzerland corresponds to the SmPC (summary of product characteristics)). Reference to studies is only allowed if they fulfil the requirements of good clinical practice and have been published or accepted for publication (article 5(5) AWV). In addition, statements based on findings of new studies which do not correspond with the approved product information may not be used for advertisement (*cf.* decision of the Federal Administrative Court C-5490/2015). HCPs must be informed that they can request a copy of the referenced studies from the advertising company.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Endorsements by HCPs are permitted in advertisements. In any event, their content must be well-balanced, not misleading and the endorsing HCPs must be identifiable.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Comparative advertisements are permitted insofar as they are scientifically correct and based on equivalent clinical trials or published data collections (article 7(1) AWV). As long as the comparative statement is scientifically correct, the study must not necessarily be a "head-to-head" clinical trial.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Comparative advertising is permitted in Switzerland (article 7 AWV). However, the comparison has to be scientifically correct and must be based on at least clinical study or data collections, such as meta analysis and practical reports published on a scientific recognised medium. It is also possible to expressly mention the brand names of competitors. Since Swiss law prohibits the advertisement of unauthorised medicines or indications, no reference to such medicinal product or indication is permitted.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

The general advertising rules apply. In particular, advertisements may not be disguised as scientific papers and/or proceedings of congresses (article 5(4) AWV) and then be distributed to HCPs.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Advertisements directed to HCPs have to be informative (article 6 AWV). A teaser advertisement to alert HCPs that something new will follow without any additional information does not comply with this requirement.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Since the promotion of the combination use for Product A by the MAH of Products A and B would not result in an off-label advertising, one must assume that the promotion of the combination use is permitted for both products and for both MAH. However, Swiss regulatory authorities would normally request the amendment of the medical indications for both products in the product information before allowing the combination use, as pharmaceutical products can only be promoted in accordance with the published patient information.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Samples of medicinal products can only be provided upon written request of HCPs and only in small quantities. Samples must be for the smallest available dosage and contain the approved product information (article 10 (1-2) AWV).

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Swiss law allows the grant of promotional gifts and other material benefits of modest value to HCPs if such benefits are relevant to the medical practice (article 33(3)(a) TPA). Federal authorities have determined that such material benefits may not exceed CHF 300 per year and individual recipient. Irrespective of its value, gifts without relevance to the medical practice (e.g. concert tickets or a bottle of wine) are prohibited.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Any free contributions to healthcare organisations for the development of new products and for research activities in the form of equipment donations, funding of medical and technical services or in cash, are permitted. The same rules apply to donations to (public and private) institutions employing HCPs. Any donation in kind or in cash must be based on a written agreement and openly disclosed to the public in detail by the donating manufacturer of medicinal products (*cf.* rules 221–293 Pharma Cooperation Code).

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Objects, information and training materials of moderate value can be provided to HCPs if they are used for post-graduate or continuing education and are beneficial to patients. Such goods and services are not covered by the obligation of disclosure (rule 233.3 Pharma Cooperation Code).

Against it, any other pecuniary benefits that constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicinal products are generally prohibited (article 33 TPA).

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Commercially and economically justified discounts which directly reflect on the price are permitted (article 33(3)(b) TPA). Reasons for economically justified rebates may be rebates on volume, if and as far as they reduce storage and other costs of the supplier. Other than rebates granted based on economic reasons, usual commercial discounts do not need to be justified by cost saving, but may be given for the introduction of a new product or for the maintenance of a customer. Usual commercial rebates can also be volume-related.

The permissible range for rebates is not mentioned in the TPA. According to case law, (i) a rebate of 33% during one month to introduce a new product has been considered to be exceptionally high, and (ii) a discount of 1–25% may be seen as economically and commercially justifiable. According to Swissmedic, even rebates of 90% might qualify as usual commercial discounts if they are granted within a regular procurement process (*cf.* Swissmedic Journal 11/2012, p. 1054). In any case, rebates need to be transparent in a way that allows the assessment of their commercial and/or economic justifications and, eventually, their benefit to healthcare insurers and patients (article 56(3) of the Health Care Insurance Act, hereinafter "**KVG**", https://www.admin.ch/opc/de/classified-compilation/19940073/index.html, no translation in English available). In that sense, rebates have to be mentioned in receipts and invoices, as well as in the accounting records of the suppliers.

Because they reflect economic consideration, volume rebates are permitted in the following forms: (i) linear rebates or scale (for each defined of quantity) rebates; (ii) rebates on an estimated (and not on the actual) turnover; and (iii) rebates corresponding to the actual cost savings, always provided that no customer discrimination takes place.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Under Swiss law, it is possible to offer additional contingent medical or technical services upon separate remuneration or as part of the original purchase price (as a "package deal"), provided that such material benefits (i) are not bound to a minimum order quantity for the medicinal products, (ii) are clearly disclosed in receipts and invoices as well as in the accounting records of the supplier, and (iii) can be forwarded to healthcare insurers, where healthcare insurance pays for such additional medical or technical services (article 56(3) KVG).

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Even if not expressly prohibited, in most constellations refund schemes are likely not to be permitted. A refund retained by HCPs is a pecuniary benefit that should be forwarded to patients or their healthcare insurers (article 56(3) KVG). Even if forwarded to patients and healthcare insurers, refund offers may be seen as an inducement to prescribe non-appropriate medicinal products (against the principle stated in article 56 KVG). With regard to over-the-counter medicines, and taking into account the guidelines for free samples (article 19 AWV), refund schemes may be permitted, provided that they do not unnecessarily increase the use of medicinal products, if they are strictly limited in time and amount (article 32(1)(b) TPA).

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

The grant of financial contributions to the continuing medical education of HCPs is permitted to the extent that (i) there is no (direct or indirect) connection with the prescription or provision of medicinal products, and (ii) participating HCPs pay a substantial contribution to the educational costs (at least 20% (for HCPs in formation) or 33% (for all other HCPs) of all costs, including participating fees). The supporting programme shall not exceed 20% of the duration of medical educational events and of the costs thereof (see Swissmedic Journal 1/2006, p. 20 *et seqq*.). Most healthcare organisations also request that the grant of sponsoring continuing medical education does not favour individual HCPs. Finally, objects, information and training materials of moderate value used for continuing education may be provided by pharmaceutical companies (rule 143.3 Pharma Cooperation Code).

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Article 33 TPA contains specific rules on bribery in relation to interactions between pharmaceutical companies and HCPs or HCIs. In addition to these provisions, the general anti-bribery rules stated in the Swiss Criminal Code are applicable to cases of bribery in the healthcare sector (*cf.* article 322*ter et seqq*. SCC). Swissmedic has the statutory mandate to ensure compliance with pharmaceutical

advertising as well as the specific rules on bribery. Swissmedic may therefore act as prosecuting authority in this area. At the same time, the cantonal criminal authorities also have to prosecute bribery cases. The delimitation of competence between the authorities has to be assessed on a case-by-case basis.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Rules on permitted hospitality to HCPs are set off both in statutory regulations (article 33 TPA, article 56 KVG) and in the codes of conduct (rule 37 Pharma Cooperation Code). HCPs may accept hospitality contributions to their continual education and participation in scientific conferences, provided that the sponsoring relationships are kept transparent and do not qualify as granting material benefits.

If scientific conferences and events take place outside Switzerland, pharmaceutical companies may contribute to the hospitality costs only where most of the guests or the professional knowledge comes from other countries, making it more appropriate for logistic reasons to hold the event outside Switzerland (rule 376 Pharma Cooperation Code). The arrangements should be approved by the company affiliate organising and being responsible for the event, irrespective of the place where the hospitality takes place.

Also, regardless of where the scientific and educational events take place, HCPs that dispense medicinal products in Switzerland must pay a substantial contribution to the educational costs (*cf.* the answer to question 4.8). Payment for meals (including beverages) must remain on a reasonable and modest scale, subject to a maximum of CHF 150 per healthcare professional per meal for events that take place in Switzerland (rule 143.5 Pharma Cooperation Code).

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Hospitality contributions may be offered to HCPs in connection with their participation in scientific congresses. Such contributions must be confined to the journey, subsistence, accommodation and participation fees of the participating HCP. Hospitality must not include the support (sponsorship) or organisation of entertainment (e.g. sport or leisure activities) or the costs of accompanying persons (article 11(2) AWV). Also, indirect costs, such as loss of working time, cannot be compensated. A direct payment is only permitted if, and to the extent, the HCP assumes an active task during the scientific meeting (e.g. as speaker).

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Pharmaceutical companies are permitted to organise or carry out scientific congresses. In respect of such congresses, pharmaceutical companies may also be held responsible for the content. However, pharmaceutical companies cannot be held responsible for the content of scientific meetings they sponsor but do not organise – as they do not influence the content.

In any case, pharmaceutical companies remain liable for infringement of the advertising regulations, e.g. through non-permitted hospitality arrangements, during scientific meetings (article 87(1)(b) TPA).

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Pharmaceutical companies may entrust HCPs with consultancy tasks or services, such as papers and the conduct of meetings, medical or scientific studies, clinical trials, training and participation in advisory boards, and provide reasonable compensation, according to the usual standards. Such expert services are permitted insofar as they do not result in material benefits granted to HCPs. The following requirements must also be complied with: (i) there must be a justified need for the proposed consultancy task or service; (ii) the retained HCPs must be qualified to perform the tasks; (iii) no more HCPs will be entrusted than needed; and (iv) consultancy tasks or services must be documented (rule 213 Pharma Cooperation Code). In this regard, the recommendations of the SAMW "Collaboration between the medical profession and industry" guidelines (http://www.samw.ch/en/Publications/Medical-ethical-Guidelines.html) should be taken into consideration.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

HCPs are generally permitted to take part in clinical research, including post-marketing surveillance studies. Such studies must be carried out according to legal regulations and strict principles of good practices and based on a written agreement; the researchers and their co-workers must not have personal financial interest in the results of the clinical research. The recommendations of the SAMW "Collaboration between the medical profession and industry" guidelines should also be taken into consideration here.

If the researchers work for a healthcare institution (hospital, university, etc.), the clinical research has to be transparently disclosed to this institution. In addition, compensations are to be paid out on institutional separate accounts of the receiving institution. In any event, the performance of post-marketing surveillance and clinical studies must remain independent from the purchase of medicinal products by the researchers and their employers.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

It is possible to engage HCPs in promotional activities. However, HCPs who write or speak in public about matters which are the subject matter of research agreements concluded with a pharmaceutical company must clearly disclose their relationship (rule 214 Pharma Cooperation Code). Researchers responsible for or involved in a trial must not undermine their independence by participating in marketing campaigns for the product or procedure investigated.

More generally, advertisements to the public must not contain recommendations by HCPs or references to clinical research performed by them (article 22(g) AWV).

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Non-prescription medicines can be advertised to the general public (article 31(1)(b) TPA and article 14 AWV). However, no advertisement is permitted for medicines that: (i) contain narcotic or psychotropic substances; (ii) may not, on account of their composition and their intended use, be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment; or (iii) are frequently the object of abuse or lead to an addiction or dependence (article 32(2)(b) to (d) TPA). In addition, an advertisement to the general public for medicines with a recommended dosage of more than 0.5g of pure alcohol cannot be made on radio and television (article 20 AWV).

Advertisements to the public must not be misleading, incite abusive, excessive or inappropriate use of medicinal products, or be contrary to public morality and order (article 32(1) TPA). Exaggerations are prohibited, statements have to be in line with approved product information and advertisements must be recognisable as such (article 16 AWV). Specific advertisement elements that are not allowed to be used are listed in article 22 AWV.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Prescription-only medicines cannot be advertised to the general public (article 32(2)(a) TPA and article 14 AWV).

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Disease awareness campaigns encouraging patients with a particular medical condition to consult their doctor are permitted. However, if medical campaigns directly or indirectly refer to a specific prescription-only medicine (*cf.* decision of the Swiss Supreme Court 2A.63/2006, please see the answer to question 1.7), they amount to unpermitted advertisements towards the general public.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Swiss law limits the advertisement for prescription-only medicines in journals to the ones directed to HCPs (article 4(a) AWV). In line with that, press releases for developments in relation to as yet unauthorised medicines and/or indications are not allowed.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

Factual background information about the manufacture and research activities of pharmaceutical companies published in corporate brochures is not considered to be of an advertising nature, provided that no specific (prescription) medicinal products, indications or contraindications are described in detail. Detailed descriptions of medicinal products in an information brochure would circumvent the limitations on advertising for medicines.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Any direct or indirect advertisements for prescription-only medicine through meetings or the funding of patient organisations are generally prohibited. In addition, pharmaceutical companies must not require patient organisations to promote specific products. Besides that, it is lawful to meet and to fund patient organisations. Where pharmaceutical companies grant financial or other support on a significant scale to a patient organisation, they must agree such support in writing and accurately describe the nature and the purpose of such support (rule 3 Pharma Cooperation Code).

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

As such, it is not prohibited to provide items to or for the benefit of patients for free, as far as the patient is aware of the offer's gratuity and the healthcare insurance is not charged. As far as companies provide items for the benefit of patients to HCPs, the limitations described in the answer to question 4.1 apply. With regard to items provided directly to the patient, the rules of the UCA also have to be observed. In particular, it is illegal (i) to deceive the patient by means of gifts about the actual value of the offer, and (ii) to impair the patient's freedom of decision by using particularly aggressive sales methods (article 3(g) and (h) UCA).

Specific rules apply to free medicinal product samples provided to patients. Medicinal product samples can be distributed to patients under the following limitations: (i) they must be clearly and permanently labelled as "sample for free"; (ii) they must contain the approved information and texts on the containers and packing materials; and (iii) they must contain only the recommended dose for one day (article 19(1-3) AWV). Furthermore, samples of prescription medicinal products can only be distributed by persons entitled to dispend them (article 19(4) AWV).

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Switzerland has adopted transparency in clinical research with the enactment of the Federal Act on Research involving Human Beings (Human Research Act, hereinafter "**HRA**", https://www.admin.ch/opc/en/classified-compilation/20061313/index.html) and its ordinances in January 2014. All approved clinical trials must now be registered in a public registry and the results published after the trial's closure (article 56 HRA). The sponsor must register approved trials in a World Health Organization (WHO) primary registry or in the registry of the US National Library of Medicine (www.clinicaltrials.gov). Additionally, specific trial information must be made publicly available in the national language in the database of the Federal Council (article 64 *et seqq*. Clinical Trials Ordinance, https://www.admin.ch/opc/en/classified-compilation/20121176/index.html). Public access to information on clinical trials conducted in Switzerland is guaranteed by the SNCTP Portal (http://kofam.ch/en/swiss-clinical-trials-portal/). Trial information shall be registered before the start of the clinical trial.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Swiss legislation does not oblige pharmaceutical companies to disclose information about the material benefits granted to HCPs or healthcare organisations. However, article 56(3) KVG requires transparency in the grant of rebates and of other material benefits in connection with prescription medicinal products, in order to allow a proper forwarding of the same to healthcare insurers and patients.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Rule 23 *et seqq*. Pharma Cooperation Code requires the full disclosure of pecuniary benefits granted to HCPs or healthcare organisations. Pharmaceutical companies shall, in each case, disclose the pecuniary benefits annually and this information must remain accessible to the public for at least three years. Disclosure shall take place wherever possible and legally permitted, on an individual basis, to clearly identifiable HCPs with the relevant amounts paid; the remuneration for the agreed service or consultancy tasks and the compensation for the related costs of the service providers are to be disclosed separately. Companies are not obliged to disclose via a central platform but disclosure shall be done on their corporate website. The duty of disclosure applies to all pharmaceutical companies which are required to comply with the Pharma Cooperation Code. It may apply to companies that have not yet been granted a marketing authorisation. Foreign companies (apart from the Principality of Liechtenstein) cannot become members of the Pharma Cooperation Code and therefore do not need to respect these rules.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

According to rule 231 of the Pharma Cooperation Code, pharmaceutical companies shall disclose pecuniary benefits, which they grant to HCPs. The Pharma Cooperation Code also states that pharmaceutical companies shall stipulate in agreements with HCPs that the recipients of pecuniary benefits agree to disclose (rule 232). Without prior consent of the HCP, however, the pharmaceutical company would regularly breach the statutory data protection rights of that HCP by disclosing granted pecuniary benefits. The Pharma Cooperation Code is not a statute, which would allow the pharmaceutical company to justify the disclosure of the HCP's personal data without his/her prior consent. Accordingly, the Pharma Cooperation Code states that disclosure is not required if it is incompatible with the provision of data protection law (rule 234). Having said this, however, a pharmaceutical company should, whenever possible, disclose granted pecuniary benefits on an individual basis (rule 272 Pharma Cooperation Code).

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Advertisements on the internet directed to the general public are governed by the rules applicable to print advertisements. As all advertisements directed to the general public, advertisements on the internet for preparations of the sensitive groups with a potential for dependence or abuse mentioned in the medicinal product information must be submitted to Swissmedic for prior written approval (*cf*. the answer to question 1.5).

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Swissmedic requires that pharmaceutical companies must ensure that advertisements for HCPs are accessible only by them, e.g. by providing password-protected access (article 5a AWV).

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Pharmaceutical companies do not have the obligation to control the content of independent websites linked to their own website.

However, this general rule may not apply where the linked webpage is part, or appears to be part, of a company's own website or where the company is aware of the illegal content of the other webpage, but still provides a link on its own website.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

A pharmaceutical company may only publish information about the company itself and its fields of activities. No information on the single pharmaceutical products is permitted.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

The use of social media by pharmaceutical companies is not subject to specific rules. The prohibition for advertising of prescription medicines and the advertising rules set off in the TPA and AWV also apply to commercial information of pharmaceutical companies in social media.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

AWV rules have been revised and more strict rules on advertising of pharmaceutical products have come into force on January 2019. Accordingly, pharmaceutical companies must ensure that advertising for prescription medicinal products is disseminated only among HCPs (with strict rules on website access). Also, samples to HCPs can be distributed only if the HCPs only expressly request them. The distribution of samples to the public continues to be permitted, but no voucher for "free" medicinal product samples can be advertised or handed over to the consumers. Finally, a pre-control of TV and radio advertising for pharmaceutical products is no longer requested by Swissmedic.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The TPA and its implementing ordinances are currently under revision and the new provisions will likely come into force not before 1 January 2020.

Among others, the current rule on pecuniary benefits (article 33 TPA) will be replaced by two new provisions (article 55 and 56 revTPA) and a newly created Ordinance on Integrity and Transparency in the Field of Therapeutic Products.

Unlike the current rule, the prohibition of granting undue material benefits will apply only to HCPs prescribing, dispensing, using or buying prescription-only medicines (article 55 revTPA). The list of exemptions to this *per se* prohibition will be amended. The exemption of granting material benefits of modest value to HCPs remains unaltered. Rebates and refunds, on the other hand, will be allowed under the revised rule if they do not affect the choice of treatment, which is primarily the case when discounts are forwarded to healthcare insurers and patients.

As principal novelty, the revised TPA provides for an explicit transparency obligation (article 56 revTPA). All parties involved in the purchase and sale of therapeutic products (including non-prescription products and medical devices) will have to fully disclose any discounts and refunds in their receipts, invoices and accounting records. In addition, the Federal Office of Public Health will have the competence to require the disclosure of these documents at any time.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Swissmedic is very active in enforcing advertising rules, mostly upon notifications of third parties and has shown that it is willing to take a strong hand on illegal advertising of pharmaceutical products, in particular products that can be made available on the internet.

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Sarah Drukarch assists domestic and foreign corporations from a broad range of industries, including life sciences, media, ICT, and foodstuffs, with establishing and maintaining intellectual property rights and related licensing and transfer matters, also as part of national and international M&A transactions.

In the field of life sciences, Sarah Drukarch is regularly involved in the negotiations for international research and development projects, covering both pre-clinical and post-clinical set-ups. She advises manufacturers and service providers of regulated products comprehensively, for example, in connection with establishment licences, marketing authorisations, industry-specific permits, marketing, compliance and vigilance.

PESTALOZZI
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Pestalozzi is one of the leading and most respected law firms in Switzerland. It has offices in Zurich and Geneva and specialists with expertise in all areas of business law, enabling it to form customised teams to meet the needs of a vast range of international and domestic clients.

The Life Sciences practice group offers legal advice to companies specialising in life science technologies. The areas we cover range from biotechnology, pharmaceuticals, diagnostics and personalised medicine to nutraceuticals, cosmetics, food processing, biochemical and medical devices, as well as other regulated products and services. In addition, Pestalozzi supports organisations and institutions committed to research and development, the processing of digital data, technology transfer, commercialisation and distribution.

Essentially, we provide high-quality legal and regulatory advice for international manufacturers and providers of life science products and services. We represent them in dealings with the Swiss regulatory authorities or when contacting international technology clusters.

# Taiwan

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The laws and codes governing the advertising of medicinal products are the Pharmaceutical Affairs Act, the Fair Trade Act, the Pharmacist Act, the Enforcement Rules of The Pharmaceutical Affairs Act, Processing Regulation of Network Advertisement for Medicaments, the Code for Relation Between Physician and Manufacturer, the Taiwan IRPMA Code of Practices, the Medicament Sample/Gift Management Regulation, Medical Care Act and the Medicament Internet Advertising Principle.

### 1.2 How is "advertising" defined?

"Advertising" refers to the act of advertising the medical efficacy of medicaments by means of communications aimed to solicit and promote the sale thereof.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Sending the advertising materials to the internal legal department and/or an external counsel for review of legal compliance is normally arranged.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

No, there are not any legal or code requirements for companies to have SOPs governing advertising activities in Taiwan.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

1. Yes, for publishing or broadcasting medicament advertisements, pharmaceutical firms shall, before publication or broadcast, submit all texts, drawings or pictures constituting an advertisement to the central or municipal competent health authority for approval before a mass media enterprise accepts the advertisement for publication or broadcast.
2. No publication or dissemination of an advertisement for a drug may take place until a pharmaceutical firm with a drug permit licence has filled out an application form and submitted it to the central competent health authority or the competent health authority of the special municipality or county (or county-level city) along with photocopies of the drug permit licence and the approved label, usage instructions, packaging, the content of the advertisement, and a review fee, and the given health authority has reviewed and approved the above matters.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The authorities have the power to stop the further publication of that advertisement. They can insist on the issue of a corrective statement. The advertiser who is not satisfied with the disposition of the authority may file an appeal with the competent authority and sequential appeals to the administrative court and the Supreme Administrative Court.

### 1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

1. The penalty is mainly based on fines ranging from NT$60,000 to NT$5 million. If the advertiser does not stop the illegal advertising, the fine may go up to NT$25 million for each violation.
2. The competent health authorities may send their respective officials to inspect the facilities and relevant business operations of pharmaceutical manufacturers and/or dealers and may sample-test the involved medicaments. The more extensive the medicine is used, the more strictly the rules are enforced.

3. There was a case 八十四年度判字第二五五八號判決 decided by the Supreme Administrative Court holding that an advertiser's illegal advertising shall be fined. The plaintiff moved for a constitutional interpretation at the Judicial Yuan (Constitutional Court) and the motion was reviewed by the Grand Justices therein to render the 釋字第 414 Interpretation that the regulatory advertising approval or prior review system provided by the Pharmaceutical Affairs Act is constitutional.
4. Generally, the competitors cannot take direct action through the courts because the initial dispute resolution agency shall be the competent health authority to which the competitors can report the illegal advertising and receive disposition or decision from in most situations.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The better or more complete the internal self-regulatory process is, the less the supervisory and enforcement function of the competent authority will be exercised. Although the competent authorities can and do investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code, they will not intervene in the matter without exceptional cause for matters being already assessed by any self-regulatory body. The authorities generally will take up matters based on an adverse finding of any self-regulatory body.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Under the Fair Trade Act, no enterprise shall make or use false or misleading representations or symbols on any matter that is relevant to the goods and is able to affect trading decisions on goods or through advertisements, or in any other way causing it to be known to the public. The Fair Trade Commission may investigate and handle, upon complaints or *ex officio*, any involvement in the violation of the provisions of the Fair Trade Act that harms public interests. Anyone subject to damages may bring such an action.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

1. A medicine can be authorised only after various tests respectively presided by qualified professionals. If the information made available to the professionals is just for the purpose of helping pass the test, there will be no prohibition whatsoever; if interviews, news reports or propaganda containing relevant information are to imply or suggest medical efficacy for a potential marketing purpose, they will be regarded as advertisements of medicaments. Accordingly, the information for the medicines to be discussed or made available at scientific meetings or other opportunities must stay away from commercial interviews, news reports or propaganda.
2. Whether the meeting is sponsored by the company makes no difference.
3. The position with regard to the provision of off-label information is the same.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Such information shall not be published for advertising purposes. However, for research or testing purposes, scientific information can certainly be published.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Press releases regarding the testing stage or status of unauthorised medicines and/or off-label information may be issued by companies. Nevertheless, advertisement or efficacy thereof shall not be made even if it is merely in the form of an interview or news report. For medicines administered under the prescriptions of physicians or specifically designated by the competent health authorities, any advertisement thereof shall be published only in academic medical journals.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

The testing stage or status of unauthorised medicines and/or off-label information may be sent to healthcare professionals if it involves no advertisement or efficacy thereof. Healthcare professionals should request details of information in order to stay away from any violation of laws if they want to speak positively about the information or unauthorised medicine.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The ECJ judgment in the *Ludwigs* case has not been reflected in the legislation or practical guidance in our jurisdiction if the medicinal product is not featured as a sample or gift.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

As long as there is no misleading or advertising nature in the information, the information on unauthorised medicines or indications may be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

Only if the possible launch materials for medicinal products or indications as yet unauthorised does not fall under the definition of advertising, can the company involve healthcare professionals in market research exercises. There is no guideline issued for the market research of medical products.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

Under the Pharmaceutical Affairs Act, Enforcement Rules, texts and images used in a medicine advertisement shall be limited to the name of the medicine, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines, and packaging, and the name and address of the manufacturer, as initially approved by the central competent health authority. The efficacy stated in the text of an advertisement for Chinese medicine materials shall be limited to the efficacy stated in the Compendium of Materia Medica.

In addition, the name of the firm, the number of its medicine permit licence and the advertisement approval document shall be published simultaneously or disseminated together with any medicine advertisement.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

According to regulations, whenever there is any of the following events in a medicine advertising content, that content shall be deleted or its approval shall be denied: (1) content involving SEC ability; (2) using a medicine container for a prize or providing an incentive for using a medicine, likely to foster drug abuse; (3) any representation that suggests that a medicine will cure a particular disease or will improve a person's health or constitution of a particular nature, or the creation of false or misleading scenarios as a means of promoting the medicine; and (4) exaggeration of a medicine's efficacy or safety. Medicament advertisements shall not be made by warranting the efficacy or functions of the medicament by making use of the materials or information contained in a book or publications. Accordingly, this hardly leaves room for an advertisement to refer to studies not mentioned in the SmPC.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

For medicaments, endorsements by healthcare professionals in promotional materials shall not (A) borrow the name of other person(s), (B) make use of books or journals to prove their efficacy or performance, (C) promote through interview or report, and (D) promote through other inappropriate ways.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

Enough "head to head" clinical trial data would be best, although it is not required to prepare "head to head" clinical trials before making comparative claims. Nevertheless, to the least extent, there must be enough data for one's own medicament whilst having carefully studied enough clear information about the medicament of the other party to reasonably work out the comparative information. Nevertheless, according to the Taiwan IRPMA Code of Practices, comparative claims need to be entirely based on "head to head" clinical trials.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Comparative advertisements are generally governed by the Fair Trade Act. It is possible to use another company's brand name as part of a comparison as long as all information is faithfully used. Bearing in mind that all information about the advertisement needs to be approved by the competent authority, it is possible to refer to a competitor's product or indication which has not yet been authorised in our jurisdiction. Nevertheless, according to the Taiwan IRPMA Code of Practices, consent should be obtained prior to using another company's name.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There is no specific rule restricting the distribution of scientific papers and/or proceedings of congresses to healthcare professionals. The distribution, however, must not fall under the definition of advertising.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

If the "teaser" advertisement involves no information about a medicament, it relates to nothing about permission. As long as what follows is approved by the central competent health authority, the teaser advertisements may find themselves effective.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

The holder of the MA for Product A can rely upon the approved use of Product B with Product A in Product A's SmPC to promote the combination use of Product A and Product B. The holder of the MA for Product B cannot rely upon the approved use of Product B with Product A in Product A's SmPC to promote the combination use of Product A and Product B and must first apply for variation of the SmPC for Product B.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

It is possible to provide healthcare professionals with samples of medicinal products. A medicine subject to one of the following provisions may qualify as a medicine sample: (1) medical suppliers who apply for registration or improvement of manufacturing technology; (2) medical suppliers, academic research or test institutions, test commission, medical academic groups or teaching hospitals which apply for research or test use because of business needs; (3) specialist teaching hospitals or teaching hospitals higher than regional level which apply for diagnosis and treatment of critical or major patients; (4) medical equipment manufacturers which apply for a specific exhibition or demonstration of medical equipment; (5) medical suppliers which apply for educational propaganda; and (6) applicants who apply for public safety or public health or major disaster.

In addition, the approved medicine samples shall not be sold or distributed for other use; the medicine samples are for the improvement of technology and shall not be for clinical use.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

According to the Code for Relations between Physician and Manufacturer, healthcare professionals may not accept gifts or donations of money unless sponsored for fees for registration, travelling and accommodation except lecturing or a presiding premium. Nevertheless, medicinal products can be gifts if they have been issued permit licences in accordance with the provisions of the Pharmaceutical Affairs Act and the application must be made to the central health authority before donating to healthcare institutions, hospital clinics or relief agencies at all levels for charity use. Under the Ethical Code of Ethics of Civil Servants, the monetary limit is NT$500 each time if the physician is a public servant, is NT$3,000 if a gift from a legislator in a marriage, or is NT$10,000 from the same legislator in the same year.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

It is generally impossible to give gifts or donations of money to healthcare organisations such as hospitals except in the case where it is related to research or studies complying with applicable laws and the Code of Helsinki. In addition thereto, each hospital includes the following principles: (A) research compensations depend on time and efforts devoted thereto rather than the research outcome; (B) upon announcement of research results, direct and indirect sponsors should be published at the same time; and (C) the donor may not restrict the announcement of the research results.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

It is possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns if there is no express or implied consensus to introduce products of the provider according to professional ethics and this is potentially beneficial to patients according to professional expertise.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

For end consumers or pharmacies, when the medicament advertising content is likely to encourage drug abuse, such as exchanges of medicament containers for prizes or the provision of incentives, this will violate the Pharmaceutical Affairs Act and Consumer Protection Act. For institutions or hospitals, volume discount is legal as long as the advertising content is approved.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

It is possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products, provided that the medicinal products are sold at a reasonable price. Commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") are acceptable if again, the medicine is effective and the purchase price is reasonable.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

It is possible to offer a refund scheme if the product does not work provided that the advertising content has been approved by the competent authority. It makes no difference whether the product is a prescription-only medicine, or an over-the-counter medicine where the former can only appear in academic pharmaceutical publications.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

The pharmaceutical companies may sponsor continuing medical education provided the above rules or spirits, especially those in questions 4.3 and 4.4, apply. Specifically, the pharmaceutical company should not interfere in the meeting arrangements, the announcement of the thesis or results or choice of speaker, and can only sponsor the general expenditure of the meeting.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Only when healthcare professionals provide their services in a public healthcare organisation will the anti-bribery rules apply to them. If they do not work there, only the perfidy crime in the Criminal Code is applicable, which provides that a person who manages the matter for another, for the purpose of taking an illegal benefit for himself, or a third person, or of harming interests of his principal and who acts contrary to his duties and thereby causes loss to the property or other interests of the principal, will be sentenced to imprisonment for no more than five years or detention; *in lieu* thereof, or in addition thereto, a fine of no more than NT$500,000 may be imposed. The competent authorities for pharmaceutical advertising may fine or exercise administrative measures, e.g. shutting down the business of the pharmaceutical company. Nevertheless, criminal evidence needs to be provided to the anti-bribery/anti-corruption authorities, i.e. the courts for enforcement. Although the court may investigate anything including a breach of the advertising rules for the pharmaceutical competent authority to exercise its administrative measures, it is normally interested in the anti-bribery legislation only. Certainly, a breach of the advertising rules may bring forward both an administrative measure from the pharmaceutical competent authority and a disciplinary disposition from the self-regulatory body.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

According to the Code for Relations between Physician and Manufacturer, healthcare professionals may not accept gifts or donations of money unless sponsored for fees for registration, travelling and accommodation. It makes no difference if the hospitality offered to those healthcare professionals takes place in another country. Arrangements are not required, but it is recommended that it be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place. According to the Code of Practices issued by the Taiwan International Research-Based Pharmaceutical Manufacturers Association, the threshold applicable to the costs of hospitality or meals provided to a healthcare professional is NT$3,500 per day.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

It is possible to pay for a healthcare professional to attend a scientific meeting under the Code for Relations between Physician and Manufacturer, for fees for registration or enrolment, travelling and accommodation. Accordingly, it is impossible to pay him for his time. Furthermore, according to the IRPMA Code of Practices, the compensation for giving a speech or lecture is capped at NT$5,000 per hour, while a presiding instance is NT$10,000.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

There is no specific provision for such extent, and it should be judged on the basis of the totality of circumstances. Nevertheless, the meeting organiser needs to publish the sponsor, and announce the commercial interests and the relation among the organising entity, speakers, presider and the sponsoring company. Further, it is required that what the physician announces in the meeting shall conform to scientific empirical principles and have balanced discussions of alternative treatment staying away from the influence of the sponsoring company.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

It is possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards) if there is no involvement in a physician's integrity or violation of obligations to patients and such position and commercial interests are disclosed. According to the Code for Relations between Physician and Manufacturer, any professional judgment or obligations for patients a physician has shall not be affected because of advising or consulting for the manufacturer where upon rendering a speech, article or report, subordinate or other relation with the manufacturer shall be announced. Furthermore, according to the IRPMA Code of Practices, the compensation for advisory services in each meeting is capped at NT$10,000.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

It is possible to pay healthcare professionals to take part in post-marketing surveillance studies because there is no specific law directed to govern this act. The most relevant regulations may be the Code for Relations between Physician and Manufacturer. According to this Code, any interaction between physician and manufacturer should be publicly disclosed, avoid any conflict of interests and have implemented the autonomy of clinical judgment according to the best interests of patients. The pharmaceutical company may be required to explain why and how the paid healthcare professionals may take part in post-marketing surveillance studies under the above principles and other applicable disciplines discussed above.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

The same as above, it is possible to pay healthcare professionals to take part in market research involving promotional materials because there is no specific law directed to govern this act. Again, the most relevant regulations may be the Code for Relations between Physician and Manufacturer. Since the promotional materials need to be reviewed for approval by the competent health authority, if the pharmaceutical company is confident to disclose, as required in the promotional materials, that the healthcare professionals are paid to take part in the market research, such act is very likely to be legal.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, it is possible to advertise non-prescription medicines to the general public. For publishing or broadcasting medicament advertisements, pharmaceutical companies shall, before publishing or broadcasting, submit all texts, drawings or pictures constituting an advertisement to the central or municipal competent health authority for approval, and shall forward the approval to mass media enterprises for verification. In addition, medicament advertisements shall not be made in any of the following manners: (1) to publicise the medicament by making use of the name of other person(s); (2) to warrant the efficacy or functions of the medicament by making use of the materials or information contained in a book or publication; (3) to publicise the medicament by means of releasing an interview or news report; or (4) to publicise the medicament by any other improper means.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Strictly or generally speaking, it is impossible to advertise prescription-only medicines to the general public. Where medicaments are required to have the prescriptions of physicians for administration or to have been specifically designated by public notice(s) made by the central competent health authority, the advertisements thereof shall be published only in academic medical journals. The other restrictions are similar to those mentioned in question 6.1.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

As long as there is no mentioning of any medicine, disease awareness campaigns are helpful to the general public, so they are permitted. Nevertheless, there must be no controversy about the disease and there must be more than just medicines from more than a specific pharmaceutical company for treating that disease.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

If related to advertisements, it is not possible to issue press releases concerning prescription-only medicines to non-scientific journals. If referring only to developments, scientific discussions or objective balanced observations, press releases are free regardless of whether medicines or indications have been authorised.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

As long as the advertisements are not irrelevant or subject to misleading exaggeration, there are no restrictions applicable to descriptions of products or research initiatives in corporate brochures/annual Reports. The answers should be in the Company Act and Securities Exchange Act, in promoting the corporate future for investments from the general public, such descriptions should include possibilities of negative or futile developments of products and research initiatives for fair or balanced considerations by the general public.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

Such act is permitted under the Taiwan IRPMA Code of Practices provided that the pharmaceutical company shall not ask for sole sponsorship by its own independent funding. Nevertheless, it is not seldom found that a specific organisation or activity is sponsored by only one company.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Yes, companies may philanthropically provide approved items or provide, on a commercial interests-based intent, non-sale items to or for the benefit of patients. The latter situation is governed under Medicament Sample/Gift Management Regulation (MSGMR). The item must have been approved under the Pharmaceutical Affairs Act before it can be petitioned by the central health authority for donations at all levels of healthcare institutions, hospital clinics or relief agencies as charity use.

According to Article 4 of MSGMR, medicament samples or gifts shall be detailed with the name, manufacturer, origin, specification or packaging form and quantity in the application explaining the reasons and use with a copy of the applicant's qualification documents and relevant materials provided in Articles 7 to 15 of the information. Only when approved by the central health authority, can samples or gifts be made, imported or fetched. The applicant's qualification documents refer to the patient's identity card or passport, the manufacturer's licence or the registration licence of the institution or group.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

According to the Medical Care Act, any company attempting to conduct clinical trials (except for those with the purpose of evaluating bioavailability and bioequivalence of generic drugs) generally should formulate a plan and obtain approval from the central competent authority, or be so entrusted by the central competent authority. In addition, after the central competent authority approves the clinical trials, the details of the clinical trials shall be forwarded to the Medicament Evaluation Center for publication.

The details to be published include: (1) the test commission/sponsor's name; (2) the test medicament name/ingredient/dose/dosage form; (3) the test plan number; (4) the test plan title (name); (5) the test purposes; (6) the indications; (7) the test hospital; (8) the test phase; (9) the period that the test is expected to be performed; (10) the test contact name and contact telephone number; (11) the main inclusion/exclusion conditions of the test; and (12) the number of trials.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There appears no such requirement in the legislation in view of the decision of Médecins Sans Frontières (MSF) to decline Pfizer's 1 million pandemic vaccine donation through considerations that similar action may be used by the pharmaceutical company as an excuse to increase medicament prices in the future. Nevertheless, the Code for Relations between Physician and Manufacturer provides that a healthcare professional may not accept money or its equivalent from the manufacturer. While healthcare organisations or patient organisations need to prepare and disclose the financial statement, abnormal or unusual transfers of value normally invite public concerns and inspection.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

There is a document, Ethics between Physician and Business, providing a business's self-regulatory code that monetary or goods donation or assistance should be recorded about the nature and not premised with potential commercial interests.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

The company should reflect on whether it should have the disclosure agreement in advance, or whether they should not engage in a possibly illegal action or not cooperate with such an individual in the future. If the action is definitely legal, they may report such action to the institution or organisation in which the individual serves, or consider not cooperating with this individual in the future.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Internet advertising for medicaments is regulated under the Medicament Internet Advertising Principles in the unique form of a flowchart. Generally speaking, this is successfully controlled at the basic level.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Under Medicament Internet Advertising Principles, the content of a website relevant to a prescription-only medicine and intended for healthcare professionals must be approved by the central health company authority. For a monitored website, there must be a monitoring software for discriminating/recording: (A) a medical personnel's certificate number; (B) a member's name; and (C) the entry information.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

Under Medicament Internet Advertising Principles, if the website is

owned by a medical supplier who holds a permit licence and the intended information does not relate to advertisement, product information can be included for access by the general public.

For a website not owned by a medical company holding a permit licence: (1) if the content of the website relates to a prescription-only medicine, the content can only be browsed by healthcare professionals; and (2) if the content of the website relates to an over-the-counter medicine, the content can be browsed by the general public. All these contents need be approved by the health competent authority. There is no rule governing the reverse linking of an independent website to a company's website. Nevertheless, if the content in the independent website or the product information in the company's website through a reverse linking violates the Medicament Internet Advertising Principles, the company will be held responsible. It goes without saying that the content or information shall not violate the Fair Trade Act.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Under Medicament Internet Advertising Principles, product information includes (1) for western medicine or medical instruments: (1) the name of the medicament, its dosage form, prescription content, dosage, usage method, efficacy, guidelines, and packaging, and the name and address of the manufacturer, as initially approved by the central competent health authority; (2) the complete approved medicament instruction sheet and medicament packaging or physical appearance of the medicament; (3) the indication of "export only" on the instruction sheet if applicable; and (4) for the first level of medical instruments, only identifying content of specifications, photos and approved code of classification.

Under Medicament Internet Advertising Principles, product information further includes (2) for Chinese medicine: only (1) the name of the medicament, its dosage, dosage form, prescription content, usage method, efficacy, guidelines, and packaging, and the name and address of the manufacturer, as initially approved by the central competent health authority; and (2) photos of the physical appearance of the medicament conforming to the approved label instruction sheet.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There is no specific rule, laws, or guidance controlling the use of social media by companies, but if the content disseminated through the social media contains information implying or suggesting medical efficacy, it shall be regarded as the advertisements of medicaments and shall adhere to provisions under the Pharmaceutical Affairs Act, the Pharmaceutical Affairs Act Enforcement Rules, the Fair Trade Act, the Medicament Internet Advertising Principles and others as discussed above.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

On January 6, 2017, the Grand Justices of Constitution Court handed down 釋字第 774 and held invalid Article 24(2) of Regulations of Cosmetic Hygiene Management stipulating "before publicising or advertising any cosmetic product, the manufacturer or dealer thereof shall first submit to the central, municipal or county (city) competent health authority for approval all the text, pictures and/or oral statements contained therein, and shall subsequently present the approval letter or certificate to the relevant mass propagation institutions for verification". That is, advertising any cosmetic product does not need prior review by the competent health authority anymore. 釋字第 774 may have some impact against 釋字第 414 which, as mentioned in question 1.7, held that the advertising prior review system provided by the Pharmaceutical Affairs Act is constitutional. Most jurisprudents, however, opine that the nature of medicaments is different from that of cosmetic products, so 釋字第 774 may not overrule 釋字第 414.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

There is no sign of any significant developments to be expected in the next year.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Recently, as online shopping has become more and more popular, many negligent people started to set up online stores and online auctions to sell medicaments, condoms, OK Bands, pregnancy test sticks, tampons, earmuffs, hot and cold compresses and other medical instruments. These products, however, cannot be sold online under the Pharmaceutical Affairs Act and relevant regulations. Many violation cases have been found and we believe that the competent health authority may increase their efforts in inspecting and curbing these illegal activities.

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DEEP & FAR Attorneys-at-Law

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Deep & Far prosecutes worldwide patent matters for local clients. For international or foreign clients, Deep & Far prosecutes patent matters mainly in Taiwan, significantly in China & Hong Kong, and with minor representation in Macau, Singapore, Korea and Japan. Deep & Far prosecutes in every field, such as mechanics, chemistry, pharmacy, biology, electronics, optics, telecommunications, and computer sciences.

# Turkey

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Promotional activities of human medicinal products in Turkey are regulated under the Pharmaceuticals and Medical Preparations Law no. 1262 ("Law no. 1262") and the Regulation on the Promotion of Human Medicinal Products ("Promotion Regulation") which was promulgated based on Law no. 1262. Additionally, promotional activities are further regulated under guidelines published by the Turkish Medicines and Medical Devices Agency ("TMMDA").

The Terms of the Regulation on Commercial Advertisements and Unfair Commercial Practices, which is a secondary legislation to the Customer Protection Law no. 6502, is also applicable complementarily in matters related to promotion of human medicinal products.

In addition to all of the above, independent organisations such as the Association of Research-Based Pharmaceuticals Companies ("AIFD") or the Pharmaceuticals Manufacturers Association of Turkey apply their principles and rules, such as the AIFD Good Promotion and Communication Principles ("AIFD Principles"). Member companies are obliged to comply with these principles and rules.

### 1.2 How is "advertising" defined?

Under the Promotion Regulation, "promotion" is defined as all activities organised or sponsored by marketing authorisation/licence holders aimed to provide information related to the medical and scientific characteristics of human medicinal products, enteral nutritional products and medical foods to healthcare professionals. The activities of product promotion representatives ("PPR"), announcements or notifications in medical or professional books or magazines, and activities such as scientific meetings and product promotion meetings are included within the scope of promotional activities.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Pharmaceutical companies in Turkey generally evaluate promotional materials within their internal approval system organised in compliance with the global operation procedures. Both global headquarters and local affiliates of these companies have the internal control and approval system such as scientific medical units, responsible for the compliance of the promotional materials.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

It is not mandatory for companies to have specific standard operating procedures ("SOPs") governing promotional activities under Turkish legislation. However, marketing authorisation/licence holders are obliged to internally establish a unit that ensures promotion activities related to the products the marketing authorisation/licence of which is held by the company complies with relevant legislation and this unit shall employ only physicians, dentists or pharmacists ("Scientific Function"). One of the marketing authorisation/licence holders is to establish a Scientific Function responsible and assign a responsible personnel among the function personnel for these activities.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Promotion can be targeted at physicians, dentists and pharmacists by using promotional material and/or organising/supporting scientific meetings and product promotion meetings and/or visits to physicians, dentists and pharmacists by product promotion representatives. Within this scope, the approval and permit mechanism differs in accordance with the promotion procedure. For example, it is not required for promotional materials which will be used in promotional activities to be presented for approval from the competent authorities. However, these materials can be inspected by the Ministry of Health upon any complaints/*ex officio*. For promotion via organising/supporting scientific meetings and product promotion meetings, notification to and approval of the Ministry of Health is required.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

Ministry of Health officials may decide on several sanctions, such as halting promotional activities regarded to be in violation of the relevant legislation, to ban companies from promotional activities for a certain period, or to impose administrative monetary fines.

Additionally, as the promotion of human medicinal products are regarded within commercial advertising activities, in case the relevant legislation is breached, the Advertisement Board may impose certain sanctions, such as suspension, correction with the same methods, administrative monetary fines or a three-month precautionary suspension.

In case the Advertisement Board or the Ministry of Health decides to impose such a sanction, an administrative application can be made to the institution imposing the sanction for its removal. This application is not a requirement for a lawsuit. A lawsuit may be filed for the annulment of a sanction imposed by the competent authorities before administrative courts, following rejection of an administrative application, or without any such application. However, a lawsuit filed before administrative courts will not prevent enforcement of the relevant decision.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

Several sanctions are stipulated regarding the promotion of human medicinal products. These sanctions are warning, suspension of promotion and banning companies from promotional activities and administrative monetary fines, and they are decided by the Ministry of Health. These sanctions can be applied collectively or separately. The Advertisement Board also has the authority to impose penalties, such as suspensions or administrative fines.

Administrative authorities have the authority to inspect promotional activities and all materials or methods used in these activities, either *ex officio* or upon complaints. Competing companies have the right to file complaints before administrative authorities directly, as well as lawsuits related to unfair competition in case of promotional activities contrary to the relevant legislation.

Many suspensions, warnings, administrative fines and bans from promotion have been decided by the administrative authorities of Turkey.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

In 2011, the Turkish Medicines and Medical Devices Agency were established to serve human health by developing and executing regulatory, supervisory or instructive policies related to pharmaceuticals, medical devices and cosmetics products. TMMDA has regulatory, supervisory and sanctional authority over all kinds of activities of pharmaceutical companies.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

Unfair competition conditions and the relevant legal remedies of the Turkish Commercial Code ("TCC") shall be applicable in unfair competition cases arising from promotional activities. Accordingly, unfair competition lawsuits can be filed pursuant to the TCC in cases of promotion by misleading statements about products, comparison to the business or trademark of a competitor company by derogatory remarks, or similar violations. TCC also specifies unfair competition conditions as crimes, and stipulates that these violations can be penalised by prison sentences, depending on the extent of the violation.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Promotion regulation limits the off-label promotion of human medicinal products. Accordingly, the list of promotional activities below cannot be performed:

- Promotion of products without marketing authorisation or licences.
- Promotion of products with marketing authorisation or licences in areas of use other than those approved by the TMMDA.
- Products approved by the TMMDA to be procured from abroad via prescription that have marketing authorisations or licences pursuant to relevant legislation but are unavailable in the domestic market; except for pharmacovigilance-related promotional activities of products purchased in accordance with alternative reimbursement models of the Social Security Institution and notified to the TMMDA.

However, it is possible for products without marketing authorisations to be promoted in international congresses organised in Turkey and to healthcare professionals upon their written requests by the scientific function of companies, as an exception.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

As also explained under question 2.1, information related to products without marketing authorisations or off-label use within international congresses organised in Turkey and/or to healthcare professionals via scientific functions of marketing authorisation/licence holders may be transmitted upon written requests. However, there is no clarity as to whether this information can be published or not.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

Pursuant to the Promotion Regulation's article 5/3, products cannot be directly promoted to the public, over any type of public media and communication platform including the internet, via programmes, movies, TV shows, news programmes or similar methods. This rule is applicable for products with or without marketing authorisations, or off-label use.

However, newspaper/magazine announcements made with the approval of the TMMDA that announce the supply of products to the market to healthcare professionals is not included within the scope of this rule. In such announcements, the same font as the packaging approved by the TMMDA shall be used, and the announcement shall not include any information/wording that is not included on the packaging approved by the TMMDA.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

According to article 6/2 of the Promotion Regulation, information related to products without marketing authorisation or licences can be provided directly to healthcare professionals upon their requests, by Scientific Functions of marketing authorisation/licence holders.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

The decision has no effect on Turkish legislation, as Turkey does not fall under the jurisdiction of ECJ.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

According to article 4.2.6 of AIFD Principles titled Notification of New Products and New Approved Usage Areas; sending information and product claims to health institutions or health insurance boards for consideration in following annual budgets does not violate the Principles. Under the AIFD Principles, it is possible for information related to products without marketing authorisations to be shared with health institutions, for the purpose of budgetary planning.

However, the Regulation Promotion and the Law no. 1262 do not include any terms on this matter.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

The Promotion Regulation does not include any rules regarding the principles of market research. There is no legal obstacle for a pharmaceutical company to conduct market research on competing products and to include a healthcare professional in this research. In such case, companies and healthcare professionals can sign agreements related to consultancy services. However, in case any fees paid to a healthcare professional exceeds 10% of the gross monthly minimum wage (approximately 40 EUR as of 2019), a transfer of value notification must be made to the Ministry of Health.

Other than this, AIFD Principles stipulate that market researches cannot be made with the purpose of promotion. Thus, the activity must be differentiated from promotion when receiving services from healthcare professionals.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

According to article 6 of the Promotion Regulation, promotion of a product must adhere to information and data within the scope of indications or usage areas approved by the TMMDA. Promotion includes informative and proven medical information related to the characteristics of the product, aimed to allow healthcare professionals to form their own opinions on the therapeutic value of the product.

In case promotion is made by using quotes, schedules and other visual material from medicine magazines or other scientific works, these materials must be used by representing the original use and presenting all resources completely.

Also, promotion cannot be made by using misleading, exaggerated or unproven information that unnecessarily encourages the use of the product or giving rise to unexpected, dangerous situations, or by using visuals that are attractive or not directly related to the product itself.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

The usage areas approved by the TMMDA are specified on the prescribing information (packaging insert) of the pharmaceutical. Promotion of the product must adhere to the prescribing information. Promotion of products in areas other than those approved by the TMMDA is regarded as off-label promotion and is prohibited. Additionally, it is not allowed for promotion to be made by using misleading, exaggerated or unproven information that unnecessarily encourages the use of the product or giving rise to unexpected, dangerous situations, or by using visuals that are attractive or not directly related to the product itself.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

Article 5 of the Promotion Regulation specifies that healthcare professionals cannot be involved as actors in the promotion of products without the permission of the Ministry of Health. Similarly, universities, healthcare-related professional organisations, associations and foundations cannot be involved in promotional activities without Ministry permission.

In addition, article 16 of the Regulation on Commercial Advertisements and Unfair Commercial Practices sets forth that "no visuals, declarations or references can be included in advertisements related to or creating the impression of health claims of doctors, dentists, veterinarian physicians and pharmacists or health institutions regarding a product or service".

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

The Promotion Regulation does not hold specific rules regulating the use of comparative claims. Within the scope of the Promotion Regulation, all claims used in promotion must be capable of scientific proof and compliant with the prescribing information. However, the Regulation on Commercial Advertisements and Unfair Commercial Practices, which is a complementary legislation for promotion, includes conditions for comparative advertising. Please see question 3.5 for more detailed information.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

As stated in question 3.4, the Promotion Regulation does not regulate comparative promotion. However, the Regulation on Commercial Advertisements and Unfair Commercial Practices, which is a complementary legislation for promotion, sets forth the conditions for comparative advertising. Accordingly, the following conditions are required for comparative advertisements:

- Advertisements shall not include the product name, trademark, logo, commercial title, business title regarding competitors.
- Advertisements shall not be deceptive or misleading, and shall not cause unfair competition.
- The compared products shall be aimed at the same needs.
- Comparison shall be objective.
- Claims shall be proven with scientific tests, reports and documents.
- Products, services, activities or other characteristics of competitors shall not be discredited or defamed.
- Advertisement shall not cause confusion regarding trademarks, commercial title, business name or other separating signs or goods and services.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

According to article 6 of the Promotion Regulation:

- promotion shall include informative and proven medical information related to the characteristics of the product, aimed to allow healthcare professionals to form their own opinions on the therapeutic value of the product;
- in case promotion is made by using quotes, schedules and other visual material from medicine magazines or other scientific works, these materials must be used by representing the original use and presenting all resources completely; and
- promotion shall not be made by using misleading, exaggerated or unproven information that unnecessarily encourages the use of the product or giving rise to unexpected, dangerous situations, or by using visuals that are attractive or not directly related to the product itself.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Promotion legislation does not specifically regulate "teaser" advertisements. However, newspaper/magazine announcements can be made with the approval of the TMMDA to announce the supply of products to the market to healthcare professionals.

In addition, AIFD Principles define short announcements used only in medical magazines, including the commercial name of the product, INN names of active ingredients and the name of the company, without any claims.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

In accordance with the legal regulations issued by TMMDA and in accordance with international ethical principles, it is not possible to promote off-label use of the products and conduct promotional activities in this regard.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Pursuant to the scope of article 9 of the Promotion Regulation, free samples can be distributed only to physicians, dentists and pharmacists, provided that the following conditions are met:

- The marketing authorisation/licence holder shall set up an adequate system of records and control for the production, importation and distribution of free promotional samples.
- As a rule, free samples shall be reduced in size.
- The wording, "Free promotional sample – not for sale", shall appear on the outer packaging of promotional samples. A copy of the SmPC and the PL, if available, shall be provided with the promotional sample.

- Free samples of some pharmaceuticals, determined by international conventions and official authorities, may not be distributed.
- Promotional samples shall not be used as an investigational product during a clinical trial.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

As regulated under article 6 of the Promotion Regulation, no benefits, whether in cash or in kind, may be provided, offered or promised during the promotion of products to physicians, dentists or pharmacists. Likewise, the aforementioned healthcare professionals are prohibited from accepting or requesting any incentive during the course of such promotional activities aimed at them.

However, it is possible to give symbolic, evocative materials to physicians as promotional materials. Symbolic materials, the monetary value of which shall not exceed 2.5% of the minimum monthly wage (approximately 10 EUR) and which physicians, dentists or pharmacists may use while practising their professions are included in the scope of promotional materials determined in the Promotion Regulation article 4. Although it is accepted to give symbolic materials to healthcare professionals, AIFD member companies cannot provide symbolic materials in accordance with the AIFD Principles.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

As regulated per article 6 of the Promotion Regulation, marketing authorisation/licence holders may make donations to public healthcare institutions or organisations, and non-profit healthcare agencies, institutions and organisations if the following conditions are met:

- Tender decisions concerning products within the scope of this Regulation shall not be influenced, unfair competition shall not be caused.
- The donation shall not lead to any unethical transactions which may be associated with any purchase of products.
- The donation shall not encourage the prescribing of a specific product.
- The intention shall always be to improve either research, training, health or care given to patients.
- The donation shall not be utilised by any individual person, but the entire organisation or institution.
- Only the name of the marketing authorisation/licence holder shall appear on the donated materials, while product names shall not appear.
- The donation shall be included in the official registers of the marketing authorisation/licence holder.
- Any donation of medicinal products, laboratory kits or similar items for use in clinical trials shall be made directly to the principal investigator.
- Healthcare institutions and organisations shall only accept donations by receiving permission from their central organisations, or in line with the relevant guidelines issued by their central organisations.

The marketing authorisation/licence holder may transfer any values exceeding 10% of current gross monthly minimum wage (approximately 40 EUR) to healthcare institutions and organisations only with the written approval of the authorised supervisor and provided that the transfer of value is notified to the TMMDA.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

One of the basic principles of promotion as set forth in the Promotion Regulation is that product promotion shall be made with informative and evidence-based medical information about the product's therapeutic value and the characteristics of the product, which will help healthcare professionals to form their own opinions. Thus, it is not possible for companies to influence the physician's prescription decision in any way. In order for all of the promotional activities to be carried out, it should be ensured that healthcare professionals help to form their own opinions about the therapeutic properties of the product. In all of the promotional activities, the aim is for healthcare professionals to be able to form their own opinions about the therapeutic properties of the product. Where these rules are breached, sanctions are applied within the framework of the answers given in question 1.7.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Regulations related to pharmaceutical products do not include clear provisions preventing volume-related discounts. This subject should be evaluated under anti-trust and competition law. Some opinions have been voiced in accordance with the pricing communiqué, stating that the communiqué regulates profit margins and extra discounts shall not surpass established profit margins. However, this view is contentious since the pricing communiqué regulates the resale price. Therefore, it should be noted that the pricing communiqué shall not be applicable for the determination of the commercial profit margin. The opposite application would interfere with the freedom of conducting business as laid out in the Constitution. At this point; the regulation on destructive price applications and abuses of dominant position should be taken into account in order to comply with competition law.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

It is regulated within the scope of article 6/8 of the Promotion Regulation that; no benefits, whether in cash or in kind, may be provided, offered or promised during promotion of products to physicians, dentists or pharmacists. Likewise, the aforesaid

healthcare professionals are prohibited from accepting or requesting any incentive during the course of such promotional activities aimed at them.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

The procedures and principles regarding the investigation of products that are suspected to be defective in terms of the health and safety of consumers, or found to be defective or deemed as inconvenient to be used; and the market withdrawal process, if necessary, is regulated by the Withdrawal Regulation promulgated on 19.11.2015. Reasons for withdrawal in this Regulation include, but are not limited to, any quality faults, effectiveness and safety issues, results outside specifications, packaging defects, marketing authorisation/licence incompatibility, non-compliance with legislation and non-compliance with the rules of Good Manufacturing Practices.

Responsible firms and health institutions are obliged to inform the TMMDA immediately about the products that are suspected or found to be defective. Notices made to the TMMDA regarding products that are suspected or found to be defective shall be evaluated urgently. After evaluating all available information, the TMMDA may prevent the distribution of all relevant or whole batches and may require necessary and appropriate measures to be taken.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

The requirements for marketing authorisation/licence holders to support scientific meetings and product promotion meetings are set forth in article 7 of the Promotion Regulation, titled "Scientific Meetings and Product Promotion Meetings". It is stipulated that marketing authorisation/licence holders may support the registration, accommodation and transportation expenses of healthcare professionals participating in scientific meetings in Turkey or abroad, provided that they comply with the conditions of the number limitation conditions and the support procedure.

Again, under article 7, marketing authorisation/licence holders are obliged to inform the TMMDA about the scientific meetings and product promotion meetings they organise or support and the information of the healthcare professionals subject to the support. The TMMDA collects this information in its database.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

In Turkey, the bribery offence is regulated under article 252 of the Turkish Penal Code, which sets forth imprisonment sanctions to be imposed on real persons who commit this crime; and security measures specific to legal persons to be applied to the legal entities.

The person who accepts the bribe is required to be a public officer under article 252. However, the term of "public officer" is defined broadly within the scope of article 252, including people working in the course of public service.

Within the scope of the Promotion Regulation, it is not possible for pharmaceutical companies to provide personal benefits to the healthcare professionals in kind or in cash regardless of whether or not the healthcare professional is a public officer.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

The support of scientific meetings and product promotion meetings are organised within the scope of the Promotion Regulation. Aside from this, hospitality rules such as refreshments for healthcare professionals have not been determined.

Marketing authorisation/licence holders may provide support for the registration, accommodation and transportation expenses of healthcare professionals participating in scientific meetings and product promotion meetings. These expenditures include food expenses. An upper limit for this support to health professionals has not been established in the Promotion Regulation. However, in practice, this support should be within reasonable limits.

The marketing authorisation/licence holder is not obliged to inform the Ministry of Health if one of its foreign affiliates supports healthcare professionals.

In case direct or indirect benefits exceeding 10% of the gross minimum wage (approximately 40 EUR), other than scientific meetings and product promotion meetings, are performed for healthcare professionals, it is necessary to notify the Ministry of Health regarding this value transfer.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

Marketing authorisation/licence holders may cover the costs of registration, accommodation and transportation of healthcare professionals participating in scientific meetings in Turkey and abroad. However, payments shall not be made directly to the healthcare professionals, and instead shall be made to the organisation or organisations arranging this meeting.

It should be noted that in the event of product promotion meetings organised by marketing authorisation/licence holders, the transportation and accommodation costs of the participants, except the speakers, shall not be covered by the marketing authorisation/licence holders.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

Marketing authorisation/licence holders are obliged to notify the TMMDA about any scientific meetings or product promotion meetings they organise or support; and provide information about the healthcare professionals or students of faculties or higher education institutions educating healthcare professionals, which are sponsored.

In addition, article 5 of the "Scientific Meeting and Product Promotional Meetings Application Guideline within the Scope of the Promotion Regulation" regulates that marketing authorisation/licence holders shall apply to the TMMDA for scientific meetings to be organised or supported.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Within the framework of the general legal principles, it is possible for pharmaceutical companies and healthcare professionals to enter into service agreements. Pharmaceutical companies can make payments to healthcare professionals by signing a service agreement for consultancy services they will receive from the healthcare professional. This advisory service includes participation in Advisory Board Meetings organised by pharmaceutical companies. There is no monetary limitation in this regulation and no additional rules are foreseen.

However, for any payments made to healthcare professionals exceeding 10% (approximately 40 EUR) of the gross minimum wage, it is necessary to report the transfer of value to the Ministry of Health.

In addition to these rules, the payment made by AIFD member companies to healthcare professionals shall be in line with fair market values.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

For this type of professional service to be taken from healthcare professionals, pharmaceutical companies can sign service agreements and make payments to healthcare professionals. The responses to question 5.4 also apply to this type of service.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

There is no regulation related to market research in the Promotion Regulation. However, it is regulated in the AIFD Principles that the preparation and implementation of such market research, post-marketing surveillance studies, post-registration studies and similar practices shall not be carried out with promotional intentions. On the other hand; promotional use of scientific and statistical data obtained as a result of market research is possible. However, the stages of conducting the market research and promotion should be separated from each other. Based on these explanations, it is possible to receive service from healthcare professionals for their participation in the market research study. However, this service should not be associated with direct promotional activity.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

As per the Promotion Regulation, any promotion of products to the general public through any public media or communication channels including the internet is prohibited, whether directly or indirectly, or whether through placement in programmes, movies, TV series, news reports or similar media.

In addition, PL/indications of products that have been approved by the TMMDA may only be published in media specified by the TMMDA, or in the marketing authorisation/licence holder's own website. Apart from these media, no activities may be conducted for public promotion or information, by using the TMMDA-approved SmPC/PL/indications partially or completely. However, information on products that will be used in vaccination campaigns, organised actions to combat epidemics or other campaigns run by the Ministry of Health to promote health may be provided to the general public as they are important for safeguarding public health, upon permission of the Ministry and within the confines of principles and procedures set by the Ministry for such products.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

The statements in question 6.1 apply to this matter as well. As per Promotion Regulation, regardless of whether the product is a prescription drug or not, any direct or indirect promotion of products to the general public media is prohibited in any media.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

As per article 6/1 of the Promotion Regulation, promotion to the general public may be made for products that will be used in vaccination campaigns, organised actions to combat epidemics or other campaigns run by the Ministry of Health to promote health as they are important to safeguarding public health, upon permission of the Ministry and within the confines of principles and procedures set by the Ministry for such products.

In addition to this, it is regulated in article 20.1.3 of AIFD Principles that upon approval by the Ministry of Health, product names ("INN") and company logos may be mentioned.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

In accordance with article 11/2 of the Promotion Regulation, if a marketing authorisation/licence holder wishes to announce the

launch of a product to healthcare professionals through a press release, the TMMDA's approval should be obtained. It should be noted that this concept is regulated for products with marketing authorisations.

Within the scope of the Promotion Regulation, as per article 5 of Guidelines on Application to Free Promotional Samples' Distribution and Media Announcements and article 6.3.3 of the AIFD Principles, pictures and drawings may not be used and announcements may not be coloured. Additionally, fonts which are the same with packaging font approved by the TMMDA should be used in these announcements and the announcement should not contain information/writings which are not included in the packages approved by the TMMDA.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

As per article 5/4 of Promotion Regulation it is regulated that PL/indications of products that have been approved by the TMMDA may only be published in media defined by the TMMDA, or in the marketing authorisation/licence holder's own website and apart from these media, no activities may be conducted for public promotion or information, by using the TMMDA-approved SmPC/PL/indications partially or completely.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

According to Promotion Regulation article 6/10 marketing authorisation/licence holders may make donations to public healthcare institutions or organisations and non-profit healthcare agencies, institutions and organisations if they fulfil indicated conditions. Donations to be made to patient organisations are also included in this scope. However, such donations should be notified to the TMMDA if the amount exceeds 10% (approximately 40 EUR) of the gross minimum wage, as all other donations.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

In order to encourage the rational use of human medicinal products, offering trainings and materials are allowed by the Ministry of Health. While promotion of products to healthcare professionals is possible, any promotion of products to the general public is prohibited as per the Promotion Regulation. Additionally, in order to provide rational use of human medicinal products, training and sponsorship programmes may be conducted by submitting an application and obtaining permission from AIFD.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

In accordance with article 13 of Medicinal and Biological Products' Clinical Trial Regulation, titled Commencement and Conduct of Clinical Trials, clinical trials commenced upon TMMDA permission are registered to a database, open to the general public, with the condition to comply with personal data privacy. This database is stored in the Clinical Trial Portal (http://kap.titck.gov.tr). The clinical trial's coordination centre, the name of the principal investigator, trial name and current state also may be found in the portal.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

As per article 11 of the Promotion Regulation; marketing authorisation/licence holders shall submit value transfers exceeding 10% of current gross monthly minimum wage and made to healthcare institutions and organisations, universities, healthcare professionals and professional organisations, unions, associations and foundations with activities in the healthcare industry of which healthcare professionals are members, and non-governmental organisations founded to preserve and improve health, to the TMMDA in detail and in the format determined by the TMMDA within the next calendar year's first half.

Although it is not obligatory for companies to make information about value transfer publicly available, it is obligatory to inform the TMMDA if the value transfers are exceeding the specified amount. In addition, all information and documents relating to the value transfer pursuant to the same article should be maintained by the marketing authorisation/licence holders for a period of five years.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

The responses to question 7.2 applies to this question as well. As per Promotion Regulation it is only regulated for companies to submit transfers of value to MOH's system.

Even though making information about transfers of value publicly available is obligatory for EFPIA member companies, ARBC member companies are immunised from the obligation of making information of value transfer publicly available at least for some time.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

As per article 11 of Promotion Regulation and Transfers of Value Guidelines for the transfer of value to be made, it is obligatory for marketing authorisation/licence holders to obtain healthcare professional's written consent for acceptance of transfer of value and to submit transfer of value to the TMMDA, and to obtain the competent officer's written consent for transfers of value made to institutions and organisations defined in the Promotion Regulation,

such as public hospitals, associations operating in the healthcare sector, or patient organisations. In case consent has not been obtained, it is not possible to make a transfer of value.

## 8 The Internet

### 8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Any promotion of products to the general public through any public media communication channels including the internet is prohibited.

PL/indications of products that have been approved by the TMMDA may only be published in media defined by the TMMDA, or in the marketing authorisation/licence holder's own website. Apart from these media, no activities may be conducted for public promotion or information, by using TMMDA approved SmPC/PL/indications partially or completely.

In accordance with article 18 of Law no. 1262, if promotion or sales are done over the internet contrary to the abovementioned regulation, it shall be decided by the Ministry to prevent access immediately and this decision shall be notified to the Information and Communication Technologies Authority.

### 8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

The necessary measures to be taken by pharmaceutical companies in order to prevent healthcare professionals' access to websites are not regulated.

In this respect, according to the AIFD Principles, promotional materials of human medicinal products should be accessible only for physicians, dentists and pharmacists. It should be stated that the information in that section is only for physicians, dentists and pharmacists. An effective process (a preventive alert, password, approval mechanism) to prevent the access of others to the pages and sections meant for healthcare professionals should be inserted. It is the company's responsibility to provide the necessary restrictions to ensure that the person accessing the website is a physician, pharmacist or dentist.

In practice, companies will include queries or notices such as "Are you a healthcare professional?", or "This section is for health professionals only" in their web sites.

### 8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

The rules concerning websites, that are sponsored, are not regulated within the Promotion Regulation. However, this situation does not change the fact that companies should always act in accordance with the basic principles and rules of promotion. Thus, it is considered that content in the links that companies provide on the websites they are sponsoring should be in accordance with promotion principles and rules.

On the other hand, pursuant to the AIFD Principles, references (links) from web pages to the other sites should be made carefully, and if there is information that can be perceived as promotion for the company's products in the linked site (even if the site is accessible to the public and is not sponsored by the company), it is regulated that the company linking the content is responsible. In addition, it should be ensured that the content of the linked site is compatible with promotion principles and the linked site should be checked regularly, whether it links to the correct address.

### 8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Package leaflets and indications of products, approved by the TMMDA, may be published on the website of the company. Pharmaceutical companies can develop and promote web pages and social media platforms to inform patients and the community about diseases and current medicine practices. Since the promotion of human medicinal products to the public is prohibited in any way, no part of these pages shall be interpretable as product promotion, nor should direct or indirect links be made between disease information and company's medicines.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There is not a specific rule on this subject within the relevant legislation. However, in article 24 of AIFD Principle titled Internet, Digital Platforms and Social Media, there are regulations concerning internet sites and the use of social media. Also, as an addition to AIFD Principles, Digital Communication in Medicine Sector AIFD User Guidelines is applicable.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

Some of the provisions in article 10 of Promotion Regulation titled Medical Representatives entered into force as of the date 01.01.2019. Accordingly, as of 01.01.2019, persons who have not obtained a competence certificate from the TMMDA may not work as medical representative ("MR"). An MR ID Card is being prepared for MRs by marketing authorisation/licence holders in a format that is determined by the TMMDA. Persons who have not obtained ID Cards may not be employed as MRs. MRs show their MR ID Card at the beginning of the visit and express which marketing authorisation/licence holder they are representing.

In addition, the Presidential Decree and the Communiqué on the use of Turkish Lira were issued over September–October 2018. Following this, the TMMDA has issued an announcement based on these regulations that stated contracts between marketing authorisation/licence holders and healthcare institutions/organisations and healthcare professionals in accordance with Promotion Regulation may not be made in terms of foreign currency or foreign exchange indexed. It has been regulated that institutions/organisations/associations/unions operating in the healthcare sector should determine value transfer requests for the activities within the scope of the Promotion Regulations in Turkish Lira. However, it should be noted that if one of the parties of these agreements is a company with more than 50% foreign capital, they are exempt from this rule.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

It is expected for the Ministry of Health to make amendments to the Regulation on Promotional Activities of Human Medicinal Products. In this respect, it is known that the Ministry has a draft amendment. However, this draft has not yet been published for the purpose of obtaining the opinion of sector stakeholders. For this reason, it is not foreseeable when the new regulation will be officially published.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

During the past year, there have not been any practices that which have become prominent within the scope of promotion activities, that are not included in the legislation.

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She supports her clients in drafting, revising or updating corporate documents such as standard operation procedures, signature policies and other company documents. During her experience in regulatory and compliance matters, she has also been involved in several compliance and legal audits.

Fırat İzgi
AVUKATLIK ORTAKLIĞI ATTORNEY PARTNERSHIP

Fırat-İzgi was established by Att. Elvan Sevi Fırat and Att. Mehmet Feridun İzgi, both of whom have over 16 years of experience in advocacy and legal counselling and registered to the Istanbul Bar Association with registration number 86.

Fırat-İzgi represents a large number of global and local companies operating in various sectors in almost every field of law. As a team with a background and industry experience in life sciences, we assist clients with regard to policy issues, clinical development and trials, approval of sales and marketing, pricing, post-marketing claims of product liability, compliance, anti-trust, commercial transactions and related litigation. The firm also represents clients before the public bodies where necessary.

Fırat-İzgi team with industrial experience in fields of regulatory compliance, government and public sector relationship management, corporate governance, commercial law, administrative and tax law, advertising law and product liability, unfair competition and anti-trust, data protection, environmental law, intellectual property, commercial agreements (such as service, sales, manufacturing, supply agreements, leasing, financial leasing agreements, etc.) and human resources management.

# Ukraine

Nina Moshynska

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The main principles of the advertising of medicinal products are prescribed by article 21 of the Law of Ukraine "On advertising". Further, the Law of Ukraine "On medicinal products", the Fundamentals of Ukrainian Legislation on Healthcare Principles, the Law of Ukraine "On protection against unfair competition" and the Law of Ukraine "On protection of consumer's rights" include the provisions that relate to the advertisement of the medicinal products.

The list of medicinal products that are prohibited for advertising is prescribed by the Decree of the Ministry of Health of Ukraine "On approval of the list of non-prescription medicinal products that are prohibited for advertising".

Additional guidelines are provided by the Code of Pharmaceutical Marketing Practices. This Code should respect all members of the Association of Pharmaceutical Research and Development (APRAD).

### 1.2 How is "advertising" defined?

According to the Law of Ukraine "On advertising", "Advertising" means information about a person or goods, disseminated in any form and by any means and is aimed at the development and maintenance of advertising consumers' awareness and their interest related to such a person or goods.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no mandatory provisions as to the arrangements consisting of "sign off" or promotional copy requirements.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no mandatory provisions as to introducing SOPs or to employing personnel with a specific role. Meanwhile, under the Code of Pharmaceutical Marketing Practices, companies of the Association of Pharmaceutical Research and Development (APRAD Code) should establish and maintain appropriate procedures to ensure full compliance with the Code and its applicable laws, and to review and monitor all of their activities and materials in that regard.

A designated company employee, with sufficient knowledge and appropriate qualifications, should be responsible for approving all promotional communications.

Each company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of the APRAD Code are met.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No prior approval of advertising by any authority is required. In case the advertiser is concerned that the advertisement may be considered to be containing misleading information and be inconsistent with the relevant requirements of unfair competition laws, the advertiser can obtain a conclusion issued by the Antimonopoly authorities, regarding the conformity of advertisements to the requirements of unfair competition laws.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

In the case whereby the authorities think that an advertisement has been issued in breach of the law and/or code of practice, they have powers to request stopping the further publication of the advertisement and to request that the advertisement is amended in accordance with the legislative requirements. As a rule, authorities do not provide detailed advice as to the required amendments in advertisement content – it is the responsibility of the advertiser to publish an advertisement in accordance with the laws.

Decisions of the supervisory authority may be appealed.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

There are two authorities that have enforcement powers: State Service on food safety and protection of consumer's rights (the Service); and Antimonopoly authorities. Both of them maintain control over pharmaceutical advertising on the Ukrainian market. The law prescribes the differentiation of powers of the Service and the Antimonopoly authorities in relation to the investigation of advertising infringements.

As a rule, advertising infringements are considered by the Service. The case is to be considered by Antimonopoly authorities when an advertiser obtains unlawful advantages before competitors due to providing consumers with misleading information.

A competitor may apply to the Service informing them of an advertising infringement, but it is not possible for a competitor to apply directly to the court on this basis. Further, in the case whereby the Service decides that an infringement has been committed, the consumers that have suffered losses (it might be, *inter alia*, competitors) caused by the violation of medicines advertising rules have a right to bring a civil action against an infringer.

A penalty for failing to comply with the rules governing advertisement requirements amounts to a five-time cost of published advertising. In case it is not possible to determine the costs of advertising, the penalty amounts to up to USD 190 and higher, as a legally established penalty.

There are examples of legal actions taken against pharmaceutical companies. The Service imposed a penalty in approximately USD 2 million on a pharmaceutical company. Further, the decision of the Service was appealed by the company via the court. As a result, the decision of the Service was cancelled, in full.

The Antimonopoly authorities have a more extensive practice as to the infringements of advertising legislation. Please see question 1.9 for more information on such enforcement practice.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

In Ukraine, there is no direct relationship between self-regulatory bodies and competent authorities. Upon appropriate evidence provided by a self-regulatory body, the supervisory authority may initiate an advertising infringement procedure. While investigating the case, the authority estimates evidences, including any adverse finding of any self-regulatory body.

In the case of a breach of any code of practice that has been registered with Antimonopoly authorities, such a case is considered by the Antimonopoly authorities.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The Antimonopoly authorities investigate unfair competition actions. Concerning the violation of advertising legislation, the Antimonopoly authorities, upon the motion of third parties (i.e. a competitor), or by their own discretion, investigate the following unfair competition cases: (i) dissemination of misleading information, or incomplete, inaccurate or false statements provided in advertising materials; (ii) comparative advertising; and (iii) breach of code practice.

In the case where unfair competition is confirmed, the Antimonopoly authorities can issue a decision to impose penalties on the infringer (up to 5% of annual income for the year preceding the year of violation) and requests that the infringer stops the unfair competition activities.

Additionally, the complainant has the right to claim damages caused by unfair competition actions, via the court.

Imposing a fine of approximately USD 290,076 on a pharmaceutical company due to the dissemination of misleading information in advertising is among the notable cases investigated by the Antimonopoly authorities.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Yes, information about a medicine is available to healthcare professionals before that product is authorised. According to article 26 of the Ukrainian Law "On Medicinal Products", information about a medicinal product (concerning registered, non-registered products and products at the stage of clinical research, clinical trials) shall include the name, characteristics, treatment properties and possible adverse effects. Such information can be published in medical and pharmaceutical specialised literature, in the documents distributed for specialised medical workshops, conferences, symposia and other medical events.

It does not make a difference if the meeting is sponsored by the company responsible for the product.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Such information may be published in specialised medical and pharmaceutical literature and in the documents distributed at specialised medical workshops, conferences and symposia.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

According to article 21 of the Law of Ukraine "On Advertising", it shall be permitted to advertise: only medicinal products; medical equipment; methods of prevention; diagnostics; and treatment and rehabilitation which are permitted for use in Ukraine by specially authorised central bodies of executive power in the field of health protection in accordance with the established procedure. Further, prescription medicinal products and certain non-prescription medicinal products (the list is established by the Ministry of Health of Ukraine) are prohibited for advertisement.

However, the provisions under this article shall not apply to advertising which is conducted in specialised issues assigned for medical institutions and physicians as well as at specialised medical events such as seminars, conferences and symposia for medical subject-matters.

Thus, the press releases on unauthorised medicines and/or off-label information, can be issued in case they are aimed at a target-specialised audience (healthcare professionals).

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Providing such information to healthcare professionals is not prohibited by Ukrainian laws.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

This case has not been reflected in Ukrainian legislation since Ukraine is not an EU Member State.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Providing such information is not prohibited by Ukrainian legislation.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

It is possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications which are as yet unauthorised. It is noteworthy that healthcare professionals cannot be involved in advertising activities.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The Law of Ukraine "On Advertising" does not provide for any specific requirements to information in the advertisements directed at healthcare professionals. At the same time, the general requirements specified for advertising the medicines shall not apply to advertising medicines which are placed in specialised issues assigned for medical institutions and physicians, as well as which are disseminated at seminars, conferences and symposia for medical subject-matters.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

The general provisions of the Law of Ukraine "On Advertising" provide that the advertisements of medicines, medical products and methods of prevention techniques, diagnostics, treatment and rehabilitation, shall not contain:

- information that may give the impression that in the case of drug administration or use of the medical product, a doctor's advice is not necessary;
- information that a medicinal effect after use of the medicine or the medical product is guaranteed;
- images that depict a change of the human body, or its parts, as a result of disease or injuries;
- affirmations that conduce a fear, or evolution of such fear to sicken of a disease or worsen health condition, due to non-use of the advertised medicine, medical product or medical services;
- affirmations that promote the possibility to determine a diagnosis for diseases, pathological conditions of a person and their self-treatment with the use of the advertised medical products;
- references that the medicines, medical products and methods of prevention techniques, diagnostics, treatment and rehabilitation are the most efficient, harmless and in particular that they have no bad effect;
- comparisons with other medicines, medical products and methods of prevention techniques, diagnostics, treatment and rehabilitation with the aim of strengthening the advertising effect;
- references to the individual cases of successful use of the medicines, medical products and methods of prevention techniques, diagnostics, treatment and rehabilitation;
- recommendations or references to recommendations of the health professionals, scientists, medical institutions and organisations regarding the advertised goods or service;
- special grease payments, thanks, letters, extracts from them with recommendations, stories on the application and effect of the advertised goods or services or on behalf of individuals;
- images and mentioning of the names of popular people, cinema, TV or animated feature film stars and credible organisations; and
- information that can mislead a consumer as to the contents, origin, efficacy and patent protection of the advertised goods.

Also, advertising of medicines, medical products and methods of prevention techniques, diagnostics, treatment and rehabilitation

shall not contain references to therapeutic effects with respect to diseases that do not respond to the treatment, or are difficult to treat, and it is prohibited that doctors and other health professionals or persons whose appearance imitates the appearance of doctors, participate in the advertising.

The above provisions do not apply to advertising intended exclusively to healthcare professionals.

Regarding the reference to studies in the advertisements that are not mentioned in the SmPC, the Ukrainian legislation does not specify any such requirement or condition.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Ukrainian legislation prohibits advertising to the general public, with the participation of doctors, other health professionals or persons whose appearance imitates the appearance of doctors.

It is also prohibited for healthcare professionals to advertise medicines and medical products, for example, by including advertising information on their letterheads and specifying the producers of the medicines (trademarks), during their professional activities.

At the same time, inclusion of endorsements by healthcare professionals to the promotional materials addressed exceptionally to healthcare professionals, is not prohibited.

Such an exception applies when such information is distributed in specialised publications intended for medical institutions and doctors, and when it is distributed at medical seminars, conferences and symposia.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There is no such requirement to include data from any, or a particular number of "head to head" clinical trials before comparative claims, in Ukrainian advertising legislation.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

The comparative advertising is governed by the Law of Ukraine "On Advertising" and Law of Ukraine "On Protection Against Unfair Competition".

According to the latter, the comparative is an advertisement containing comparisons with the goods, services or activities of the other business entity.

General provisions of the Law of Ukraine "On Advertising" prohibit referring to a competitor's product or indicating such products for advertising. Literally, the law contemplates that comparisons with other medicines, medical products, methods of prevention techniques, diagnostics and treatment and rehabilitation in the respective advertisements with the aim of strengthening the advertising effect, are forbidden.

Advertising of a product or indication which had not yet been authorised in Ukraine is prohibited, so it is not possible to refer in an advertisement to a competitor's product or indication which had not yet been authorised.

### 3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

There is no special law regulating the distribution of scientific papers and/or proceedings of congresses to healthcare professionals in Ukraine.

According to the Law of Ukraine "On Advertisement", there is an exception for information placed in the specialised publications intended for medical institutions and doctors, and when it is distributed at the medical seminars, conferences and symposia. It is stipulated that the advertising restrictions for medicines of the mentioned Law do not apply to information materials such as scientific papers, proceedings of congress, etc.

### 3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

"Teaser" advertisements are not provided for by the Ukrainian legislation.

However, the Law of Ukraine "On Advertisement" contains strict requirements to the advertisement of the medicines and medical products, which should contain:

- objective information on the medicine, medical products and methods of prevention techniques, diagnostics, treatment and rehabilitation and shall be directed to be clear that the presented announcement is an advertisement, and the advertised goods are medicines, medicinal products, methods of prevention techniques, diagnostics, treatment and rehabilitation;
- recommendation to seek advice from a doctor before taking the medicine or medical product;
- recommendation regarding necessary familiarisation with the instructions for use of the medicine; and
- notification "self-treatment can be detrimental to health" which shall take no less than 15% of all advertisement space or the duration.

So, if such "teaser" advertisement does not contain all of the above requirements, it shall not be permitted.

### 3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

Off-label promotion is not allowed under Ukrainian legislation.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

According to the Fundamentals of Ukrainian Legislation on Healthcare Principles, it is prohibited for healthcare professionals to receive samples of medicinal products, accessories or appliances, for the purpose of their use in professional activities, in case such samples are being provided by the companies involved in manufacturing, sales, and/or distribution of the medicinal products, accessories and appliance. The healthcare professionals can only receive such samples within the framework of clinical research and/or clinical trials. Thus, the samples can be distributed to the healthcare professionals provided that they are not intended for their further providing to the patients.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Based on the Fundamentals of Ukrainian Legislation on Healthcare Principles, it is prohibited for healthcare professionals to receive any kind of improper incentives.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Ukrainian legislation on charity and charity organisations prescribes the rights of legal and natural persons to give donations of money and others, to natural persons, non-profit organisations and establishments such as hospitals, as well as local communities. Such donations, among others, may be aimed at healthcare assistance, support of science and scientific research. The donations cannot be given to healthcare professionals since they can be considered as improper incentives and cannot be aimed at the direct or indirect promotion of certain medicinal products or certain activities of the related healthcare professionals. The donations shall be granted and taxed in accordance with the active charity legislation and tax legislation.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Providing medical or educational goods to healthcare professionals is allowed, provided that such goods cannot be considered as "improper incentives".

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

It is possible to provide volume-related discounts as regards the purchase of the medicinal products, in case such discounts are offered to private medical establishments, clinics or other legal persons. As regards the state medical establishments, the purchase of the medicinal products and equipment is conducted by means of public tenders procedure. The public tenders procedure prescribes that e-medical establishments specify the required amount of the medicinal product, while the tender participants prescribe their price.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

The process of purchase of the medicinal products and equipment by the state medical establishments is regulated by procurement legislation and regulations on the procedure of public tenders. As regards private medical establishments and clinics, it is possible to arrange the agreements on providing additional medical or technical services or equipment as contingent to the purchase of medical products.

Also, according to the APRaD Code, no benefit in kind may be supplied, offered or promised to healthcare professionals as an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product. Providing healthcare professionals with informational or educational materials and items of medical utility is allowed as long as they are non-product branded.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Ukrainian legislation does not prescribe procedures of a refund scheme if the product does not work.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

The pharmaceutical companies may arrange sponsorships or grants relating to continuing medical education. However, sponsorship cannot be offered personally to healthcare professionals since such sponsorship can be considered as providing "improper incentives". The sponsorship of educational programmes shall not be linked to the further promotion of a pharmaceutical company or the products, or change in prescription patterns or practitioners' practice, etc.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Ukrainian anti-corruption legislation applies to the management of the state and municipal healthcare establishments, and the professionals that are employed as state civil servants. The anti-corruption laws prohibit the noted persons from receiving improper incentives from the third parties as well as receiving any gifts the value of which exceeds the established limit. Further, corruption activities include a wide range of activities which involve the use of the job and possibilities and influence related thereto, as well as unlawful use of the advertisement, with the aim to receive improper incentives or other advantages. The anti-bribery competent authorities investigate the matters that constitute violations according to the anti-bribery (i.e. anticorruption) legislation. There is no direct relation between anti-bribery investigations and proceedings, and investigations regarding the violations of the advertising legislation.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

There are no specific rules governing the offering of hospitality to healthcare professionals. However, according to paragraph 78-1 of the Fundamentals of Ukrainian Legislation on Healthcare Principles, healthcare professionals are prohibited from receiving improper incentives from business entities that manufacture and/or sell medicinal products and medical devices, or from their representatives. Additionally, if hospitality is accepted by a state civil servant or the management of state or municipal healthcare establishment, it may qualify as corruption if the value of such hospitality or entertainment exceeds the allowed gifts value, according to the applicable legislation.

Thus, medical and pharmaceutical professionals may accept offers of hospitality in the absence of signs of the improper incentive or illegitimate gifts as according to the anti-corruption legislation, if they are state civil servants or management of state and municipal establishments. It does not make a difference whether the hospitality is offered to the healthcare professionals in their home country or in another country.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

It is possible to pay a healthcare professional under a civil law contract for participation in scientific events, conducting investigations, preparing reports, speeches, etc. The noted service agreement may prescribe reimbursement of certain expenses of the healthcare professional or coverage of certain expenses directly related to the services provided (travel, accommodation, etc.).

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

This issue is not directly covered by Ukrainian legislation.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

It is possible to pay healthcare professionals to provide expert services. There are no specific restrictions. The expert services cannot be related to the advertising of certain medicinal products since this is prohibited by the law.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

The procedure of post-marketing surveillance studies is not prescribed by the active legislation. As mentioned in question 5.2 above, it is possible to pay healthcare professionals on a common law basis under a civil law contract, for their participation in studies, research, etc.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

According to paragraph 781 of the Fundamentals of Ukrainian Legislation on Healthcare Principles, medical and pharmaceutical professionals shall not be entitled to advertise medicinal products and medical devices, including the prescription of medicinal products on forms containing advertising information, and indicating medicinal products manufacturers (trademarks).

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Advertising of non-prescription medicines to the general public is possible provided that marketing authorisation has been granted for

such a medicine, and subject to the fact that they are not included on the list of medicines prohibited for advertising in accordance with the regulatory framework outlined in question 3.2 above.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Advertising of prescription-only medicines is prohibited according to the law.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Such disease awareness campaigns are not specified by the Ukrainian legislation, but they are possible if they do not contain information that usually contains an advertisement and should not create the impression that this awareness campaign is an advertisement or hidden advertisement.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

Press releases about prescription-only medicines can be included only in specialised publications intended for medical institutions and doctors, and when it is distributed at medical seminars, conferences and symposia. The same requirement applies to press releases referring to developments in relation to as yet unauthorised medicines or indications.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

The issue of describing products and research initiatives, as background information in corporate brochures or annual reports, is not specified in the Ukrainian legislation. In general, such information in corporate brochures or annual reports shall not be considered as promotional materials. So, if such description of the products or research initiatives is informational and is not intended for advertising or promotion, or does not have any of the characteristics of hidden advertising, it can be referenced by companies in their corporate brochures or annual reports.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

There are no specific rules applying to meetings with patient organisations in Ukrainian legislation. Relationships between the pharmaceutical industry and patient associations are regulated by the rules of professional ethics concluded between pharmaceutical companies, such as the APRaD Code. The main principles of such relationships according to the mentioned Code are the following:

- the independence of patient associations with respect to their policies and activities (including political decisions) shall be assured;
- collaborations between patient associations and the member companies must be based on mutual respect and trust;
- the member companies shall not ask or encourage any patient association to promote any of its products;
- objectives and scope of any partnership shall be transparent; and
- the member companies welcome the broad funding of patient associations from multiple sources.

Funding of patient organisations is not regulated by the Code, but it contains specific requirements for written documentation related to funding: the member companies that provide financial support or in-kind contribution to patient organisations must have in place written documentation setting out the nature of the support, including the purpose of any activity and its funding.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

No restrictions apply in Ukrainian legislation as to the provision of items to or for the benefit of the patients.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

The basic requirements for conducting clinical trials are provided by the MOH Order on Approval of the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials and Model Regulations of the Commissions on Ethics No. 690, 23 September 2009 (MOH Order No. 690).

Under MOH Order No. 690, a sponsor shall inform the regulatory authorities in writing on a regular basis (at least once a year after the commencement of the clinical trial or more frequently, upon request) and in case of termination of the clinical trial about the status of the conduct of clinical trials in Ukraine using the special form given in Annex to the MOH Order No. 690.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

There is no requirement in Ukrainian legislation for companies to make information publicly available about transfers of value provided to healthcare professionals, healthcare organisations or patient organisations on behalf of such companies.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

Some large companies abide by the APRaD Code. According to this Code, the following should be disclosed: registration fees; travel and accommodation expenses; fees for services; related expenses agreed in the fees for service or consultancy contracts; sponsorship agreements to manage an event; and to healthcare organisations – donations and grants (either cash or benefits in-kind) to support healthcare.

The abovementioned information may be disclosed on an individual or aggregate basis in accordance with the consent signed by healthcare professionals.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

This issue is not directly covered by Ukrainian legislation. It may be covered by the service contract between a company and individual healthcare professional.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

Ukrainian legislation does not prescribe any specific provisions as regards online advertising. The advertising legislation rules apply in a similar way with regard to online and other forms of advertising.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

It is necessary to indicate that the website content is only intended for healthcare professionals. Other website security measures can be applied on a voluntary basis.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

There are no particular rules that apply to the content of the websites that can be accessed by a link from a company-sponsored website.

The information on the noted website should correspond to general legal requirements prescribed as regards pharmaceutical advertising.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

On its website, the pharmaceutical company can publish information that corresponds to the pharmaceutical, advertising, competition and consumer protection legislation.

The information that, according to active legislation, is intended for healthcare professionals only, must have the respective indication.

For instance, the Law of Ukraine "On Medicinal Products" prescribes what information on the pharmaceutical products is permissible for publishing in Ukraine without considering the publishing of such information as advertising. This information includes the name, characteristics, health/therapeutic qualities and possible side effects.

Such information can be provided in specialised resources with regard to registered and non-registered medicinal products as well as products currently at the stage of research/trials. The website of a pharmaceutical company shall contain an indication that information provided thereon, is intended for healthcare professionals.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

There are no particular rules, laws or guidelines regulating the use of social media by the companies.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

Beginning of 2018 draft law No. 8136 "On amendments of some legislative acts of Ukraine regarding improvement of advertising of medicines, medical products, medical techniques, medical equipment, prevention techniques, diagnostics, treatment and rehabilitation" has been registered. The draft law introduces a number of changes to the Law of Ukraine "On Medicinal Products", such as vesting the MOH with the authority of approval of advertising texts and supervision of advertising compliance of the medicines. It also contains the prohibition of placing images of persons who are not doctors or other professional medical staff, who provide information on the therapeutic effect of the use of a medicine or medical product, in advertising, etc.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

No significant developments are expected in the field of pharmaceutical advertising in the next year.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

Among the general practice trends in pharmaceutical advertising, there is the possibility for advertisers to obtain conclusion of the Antimonopoly authorities in order to confirm that the advertising materials are not contrary to certain requirements for unfair competition legislation (i.e., concerning absence of misleading, false, inaccurate information, etc.). Such an antitrust compliance measure is an effective tool that is recommended prior to launching a pharmaceutical advertising campaign.

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*WIPR Leaders* recognised Mr. Bocharov as a patent leader in Ukraine and according to *The Legal 500* he is among recommended lawyers.

Maksym Bocharov has been working at Gorodissky & Partners Ukraine since 2005.

## GORODISSKY AND PARTNERS UKRAINE

Gorodissky & Partners Ukraine is a full-service intellectual property law firm established in 2000.

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The patent/trademark attorneys and IP lawyers of Gorodissky & Partners Ukraine provide a full range of services in the field of intellectual property, including inventions, trademarks, designs, utility models, copyright, computer programs, domain names, litigation, franchising, licensing, etc.

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Chapter 34

# USA



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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

**Prescription Drugs**

In the U.S., prescription drug advertising is primarily governed by the Federal Food, Drug, and Cosmetic Act (FDCA) and U.S. Food and Drug Administration (FDA) regulations and guidance. In certain circumstances, the U.S. Federal Trade Commission, as well as individual states, retain jurisdiction over aspects of prescription drug advertising as well (e.g., guarantees, pricing claims, limited-time offers, etc.).

The FDCA sets out broad requirements for prescription drug promotion and authorises the FDA to promulgate related regulations. *See* e.g. 21 U.S.C. §352(n). The FDA regulations expand on these requirements in the FDCA, adding details to the statutory framework. *See* 21 C.F.R. §202.1. The FDA has also developed various non-binding draft and final guidance documents relating to a variety of issues in prescription drug advertising, ranging from direct-to-consumer broadcast advertisements to appropriate risk communication in advertising and social media. The FDA has significant discretion in enforcing the FDCA and its implementing regulations to protect the public health of patients prescribed prescription drug products, although the breadth of the FDA's authority with respect to truthful and non-misleading claims that are inconsistent with approved labelling has been called into question by recent First Amendment case law.

**Non-Prescription Drugs**

Most non-prescription or "over-the-counter" (OTC) drugs in the U.S. are sold under the terms of regulatory monographs sanctioning a range of specific ingredients, claims and directions for use permitted in such products, without requiring FDA approval. While the FDA regulates the labelling of non-prescription drugs, it does not regulate the advertising; that responsibility largely rests with the Federal Trade Commission (FTC), with the exception of certain OTC drugs approved under new drug applications. The FTC has broad authority to address the deceptive or unfair advertising of such OTC drug products. Under 15 U.S.C. §§52–57, the dissemination of false or deceptive advertisements likely to induce the purchase of food, drugs, devices, or cosmetics is unlawful and subject to enforcement by the FTC.

### 1.2 How is "advertising" defined?

"Advertising" includes any descriptive matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the drug. *See* 21 U.S.C. § 352(n). Advertising, however, does not include "labelling" as defined in §321(m). *Id*. While "advertising" and "labelling" are legally distinct concepts under U.S. law, both advertising and promotional labelling are subject to specific FDA regulatory requirements, and both are required to be truthful and not misleading. Advertising is arguably distinct from labelling in that it does "accompany" the actual product either physically or textually. Nonetheless, various controversies have erupted over whether particular modes of dissemination of information about drug products are properly considered labelling or advertising under the FDCA, such as communications on the Internet.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

While U.S. law does not impose specific requirements on manufacturers to put "sign off" procedures in place, both the FDA and the Department of Health and Human Services Office of Inspector General, which oversees the integrity of government healthcare programmes, have indicated that they expect manufacturers to have an internal review process to ensure that advertising and promotional materials comply with U.S. law and industry Codes of Practice. U.S. government authorities have indicated that they consider an internal, inter-disciplinary sign-off process for advertising materials (in which legal, scientific/medical, compliance and regulatory personnel take part) to be an important part of a manufacturer's compliance programme, and such processes have been required as part of enforcement settlements incorporating Corporate Integrity Agreements. Generally, once advertising materials are vetted through an internal process, they are then sent to the FDA through the process described in question 1.5.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

The industry codes promulgated by PhRMA and other organisations encourage the development of appropriate processes to maintain compliance, but in large part such SOPs are driven by the range of potential enforcement risks relating to drug promotion. Such SOPs generally govern the review of promotional materials for accuracy, balance, consistency with approved labelling, and compliance with

other laws, such as the Anti-Kickback Statute, which would address the fraud and abuse aspects of payments and transfers of value associated with promotion, market research, and other commercial activities.

Under the terms of settlements with the Department of Justice and the states, and industry best practice, most pharmaceutical companies have established internal compliance frameworks, which require review processes and the reporting of violations for further investigation and action. Such SOPs should generally address issues such as (a) who participates in the review (typically commercial, regulatory, medical and legal or compliance representatives), (b) adherence to FDA and other applicable requirements and standards, such as appropriate balance and risk communication, (c) internal escalation processes when consensus cannot be reached on a promotional piece, and (d) submission to the FDA as required under applicable law.

**1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?**

As a general matter, prescription drug advertisements do not need prior approval by the FDA prior to dissemination. *See* 21 U.S.C. §352(n). However, upon dissemination, all advertisements must be submitted to the FDA Center for Drug Evaluation and Research Office of Prescription Drug Promotion (OPDP) using Form FDA 2253. *See* 21 C.F.R. §314.81(b)(3)(i). OPDP will also offer comments on advertisements submitted prior to publication, although that can significantly delay use of the materials. *See* 21 C.F.R. §202.1(j)(4). Manufacturers often submit to review proposed advertisements and promotional labelling intended for use in association with a newly-approved drug. In the case of accelerated approval products, which are approved based upon surrogate markers for effectiveness with postmarket study requirements, all promotional materials (including advertisements) intended for dissemination within 120 days of approval must be submitted to the FDA during the preapproval period. *See* 21 C.F.R. §314.550. Post-approval, promotional materials for such "subpart H" products should be submitted 30 days prior to first use. In certain circumstances – such as under a consent agreement resulting from an injunction – pre-approval of advertising may be required as part of an enforcement action.

**1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The FDA responds to violations of its advertising regulations through both informal and formal administrative processes. In instances where a manufacturer has voluntarily sought the FDA's comments on a proposed advertisement (or promotional labelling), the FDA may provide a response in the form of suggested guidance through informal communication. In such cases, manufacturers are encouraged but not legally required to accept all of the FDA's comments (though the FDA may take the position that it has placed the manufacturer on notice of a potential violation).

Where the FDA has determined that an advertisement may be or is false or misleading or otherwise violative, it may act by sending the manufacturer either an "untitled" letter or a Warning Letter. Generally, untitled letters set forth the FDA's objections to a particular advertisement and the reasons as to why the Agency believes it may violate applicable laws or regulations. Such letters ask for a response from the manufacturer and results in a dialogue with the FDA to resolve the matter to the Agency's satisfaction.

Warning Letters are generally issued when either a manufacturer has failed to comply with the FDA's requested action in an untitled letter, or where the FDA has determined that a violation has in fact occurred, particularly instances in which the violation is particularly egregious. Warning Letters set forth the particular reasons why the FDA believes the promotional material has violated the applicable laws or regulations. Warning Letters serve as notice for the manufacturer that the FDA may take further enforcement action. Warning Letters also serve as formal notice to an officer of a corporation that a violation of the FDCA has occurred, in the event that subsequent enforcement action is taken against the corporation or an individual officer. Such letters often seek specific corrective action, such as through advertising to correct the violative material or letters to healthcare practitioners.

In the last several years, the FDA has significantly curtailed its use of Warning and untitled letters in this area, focusing on cases involving significant safety issues or clearly false and misleading claims. It is generally believed that this change in enforcement posture is partially a result of changes in First Amendment case law, which, as discussed herein, significantly limits the FDA's ability to deem truthful and non-misleading information as violative.

At the time that an untitled letter or a Warning Letter is issued, the prescription drug to which the violative advertisement refers to is deemed potentially misbranded. Since distribution of an adulterated or misbranded drug can be a criminal act, manufacturers are required to withdraw and/or correct the violative advertising to the satisfaction of the FDA. Manufacturers may dispute the allegations in the untitled or Warning Letter, or seek to negotiate the scope of required corrective action with the FDA. However, subject to exceptions, the current case law generally does not deem Warning Letters to be final agency action, making it difficult to sue the FDA immediately upon receipt of a Warning Letter. Companies may pursue informal and formal dispute resolution processes, and ultimately could attempt to sue the FDA if they believe the Agency's enforcement theory is arbitrary and capricious or not authorised by law e.g., unconstitutional under First Amendment speech protections. The FDA has the option of pursuing further enforcement actions at any time, such as seeking an injunction against the company in question, or pursuing a criminal action. Such measures can also be pursued against responsible corporate officials. Third parties may also take action against companies, such as by bringing action under the False Claims Act alleging that a violative promotional activity induced claims for payment for the product under government healthcare programmes.

**1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

A prescription drug is considered "misbranded" if an advertisement fails to satisfy the requirements of the FDCA and FDA regulations. *See* 21 U.S.C. §352(n). The FDCA prohibits the introduction of a misbranded drug into interstate commerce or the misbranding of a drug already in interstate commerce. *See id*. at §331(a),(b). Further, violative advertising can be used by the FDA and other government authorities to show that a manufacturer intended a prescription drug to be used for an unapproved use, subjecting the manufacturer to

potential enforcement based on distribution of an unapproved drug. *See* 21 U.S.C. § 321(p) (defining a new drug as one whose composition has not been recognised by qualified experts as safe and effective for the intended use); 21 U.S.C. § 355(a). Potential penalties for misbranding violations include injunction proceedings, which may result in a consent agreement restraining company conduct, civil penalties, seizure proceedings, and even criminal prosecution. FDCA. *See* U.S.C. §§ 331, 333. As noted earlier, except with respect to extremely grave violations, the FDA will typically issue an untitled or Warning Letter to a manufacturer prior to pursuing these sanctions.

The FDA is responsible for the enforcement of the FDCA and FDA regulations, although the FDA must work with the Department of Justice to seek judicial review and action. *See* 21 U.S.C. 337(a). In the U.S., manufacturers are also under increasing scrutiny for advertising practices from various other parties, including state attorneys, and general and private plaintiffs such as payors and consumer groups, under a broad variety of legal theories. Unlike most criminal laws, the FDCA's criminal provisions prohibiting distribution of an unapproved new drug or a misbranded drug provide for "strict liability" for misdemeanour violations. In the context of prescription drug promotion and advertising, this means that the government need only prove beyond a reasonable doubt that: (1) a manufacturer caused a drug to be shipped into U.S. interstate commerce; (2) a manufacturer disseminated an advertisement; and (3) that the advertisement was untruthful, misleading, or otherwise violative of the requirements of the FDCA. Further, additional penalties attached to knowing or intentional violations of the FDCA and the government may use violative advertising materials as evidence of unlawful intent. As discussed earlier, recent enforcement of FDCA criminal provisions governing advertising and other promotional activities has led to massive civil and criminal fines. These provisions also provide for liability of individuals who either actively participated in the violation or were in a position to prevent or correct the violation from occurring under the so-called "Park Doctrine". *See United States v. Park*, 421 U.S. 658 (1975) (holding that an individual may be held criminally responsible under the FDCA for acts committed by his subordinates, if he was in a position to prevent or correct a violation of the FDCA from occurring and failed to do so). For example, in a remarkable 2007 case against Purdue Frederick, the prosecutors charged Purdue's CEO, Chief Medical Officer, and Chief Legal Officer with strict liability violations of the FDCA for failing to prevent or correct their subordinate employees from violating the FDCA misbranding provisions. *See* Information, *United States v. Purdue Frederick Company*, 1:07CR0029. (W.D. Wv. May 10, 2007).

Such cases continue to be pursued – often resulting in settlements in the hundreds of millions or even billions of dollars. However, as noted, the current First Amendment "free speech" case law has made it more difficult for the FDA to bring actions based on a theory that unapproved use information is *per se* unlawful without demonstrating that such communications are actually false and misleading. This has resulted in an enforcement shift to focusing on cases that also include alleged violations of non-speech-related laws, such as the Anti-Kickback Statute.

While the FDCA does not provide for a private right of action by competitors for violations of the FDCA, the Lanham Act permits claims for false advertising and unfair trade practices. *See* 15 U.S.C. §1051, *et seq*. A competitor has standing under the Lanham Act to challenge false or misleading advertising if such competitor believes that it is likely to be damaged. *See id*. at §1125(a)(1)(B). Often, competitors report potentially violative promotional material, to regulatory authorities including, but not limited to, the FDA, the U.S. Department of Health and Human Services Office of Inspector General, state attorneys general, and other regulatory and enforcement entities. The FDA also maintains an initiative to encourage healthcare professionals to report potentially violative promotional practices to the FDA through its so-called "Bad Ad" Programme, which seeks to help healthcare providers recognise false or misleading advertising and report it to government authorities. *See* FDA. Press Release. "Bad Ad Program" to Help Health Care Providers Detect, Report Misleading Drug Ads (May 11, 2010) (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm).

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

While the FDA regulates the advertising of pharmaceutical products, professional organisations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the American Medical Association (AMA), provide additional guidance for the healthcare community and pharmaceutical manufacturers. *See* question 4.2. While the FDA welcomes complaints regarding pharmaceutical advertisements and materials through OPDP, for prescription drugs, there is no general mechanism for resolving complaints through trade associations.

While typically used for issues involving the promotion of OTC drugs and other consumer products rather than prescription products, manufacturers may file a complaint with the National Advertising Division (NAD) of the Advertising Self-Regulatory Council regarding competitor advertising. The NAD is a self-regulatory body intended to provide an alternative to litigation for resolving disputes regarding advertising claims. The NAD may review any national advertisements, regardless of whether that advertisement is targeting consumers, professionals or business entities. In a NAD proceeding, a NAD attorney evaluates the express and implied messages communicated in a challenged advertisement and, after a briefing period, determines whether the advertiser has given a reasonable basis to support those messages. When reviewing health-related claims, the NAD requires competent and reliable scientific evidence, similar to the FTC's standard. The initial burden of proof is on the advertiser. If the NAD finds that an advertiser has provided a reasonable basis for its claims, the burden then switches to the challenger, who must either prove that the advertiser's evidence is fatally flawed or provide new, stronger evidence. While an advertiser may choose not to cooperate with NAD proceedings or comply with the NAD's decision, the NAD may forward the case to the FTC or applicable regulatory body for action. While the NAD's referral does not automatically result in a formal regulatory response, the potential for increased scrutiny often deters advertisers from refusing to cooperate with the NAD.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

As stated in question 1.7, the Lanham Act provides standing to a competitor to bring a false advertising claim if such a competitor

believes that it is likely to be damaged. 15 U.S.C. §1125(a)(1)(B). In addition, there is a wide array of potential federal and state antitrust and unfair competition laws that may be relevant to competitor activities.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Manufacturers generally may not promote, advertise or otherwise commercialise unapproved new drugs or unapproved uses of new drugs until they are approved by the FDA. The FDA regulations provide that: "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialisation of the drug before it is approved for commercial distribution." 21 C.F.R. §312.7(a).

With regard to unapproved new drugs, manufacturers may: (1) provide limited, balanced information to healthcare providers or patients in connection with *bona fide* clinical trial recruitment communications (which cannot make claims of safety or effectiveness about the investigational product and generally are subject to IRB review); (2) provide information to investors or securities regulators to comply with securities law requirements and/or to facilitate information about securities offerings and required material disclosures; (3) provide information about investigational drugs and the status of clinical development programmes to payors (such as insurance plan formulary committees) in connection with *bona fide* reimbursement and coverage discussions according to specific parameters set forth in FDA guidance; and (4) provide information to healthcare providers as part of *bona fide* "scientific exchange" – i.e. non-promotional, scientific or educational communications between a company's non-commercial medical or scientific staff and a licensed healthcare provider that are not intended to promote the investigational product. *See*, FDA, Drug and Device Manufacturer Communications with Payors, Formulary Committee, and Similar Entities – Questions and Answers (June 2018) available at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf.

The concept of "scientific exchange" is highly fact specific, and the FDA has issued several draft documents and policy positions which attempt to define its boundaries, though many of those policies are currently under review as the FDA and the Department of Health and Human Services consider the impact of First Amendment case law on those historical positions. In all instances, communications about investigational products must be truthful and non-misleading – in some cases, such as in the noted FDA payor communications guidance, the FDA has suggested that specific disclosures be made to ensure such communications do not violate regulations banning pre-approval promotion or false and misleading promotion.

With regard to unapproved uses of approved products (sometimes called "off-label uses"), the FDA has shown increased willingness to permit companies to provide truthful, non-misleading information about unapproved uses to healthcare providers or payors under certain circumstances. First, the FDA has clarified that certain types of product-related communications which are consistent with the approved labelling of FDA-approved products will not be policed by the FDA as inappropriate off-label promotion if they meet certain factors. These factors, which require a careful consideration of how the claim relates to the information in the Package Insert and known to the company and the FDA through pivotal studies, are spelled out in recent FDA guidance. Product claims which go beyond those "consistent with" the FDA-approved labelling pose heightened enforcement risks under the FDCA and other laws, though companies may avail themselves of *bona fide* scientific exchange communications if there is a legitimate need to communicate off-label information to physicians. *See*, e.g., *FDA, Medical Product Communications That Are Consistent With The FDA-Required Labeling – Questions and Answers* (June 2018) available at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537130.pdf.

The analysis of what falls within the definition of "*bona fide* scientific exchange" is highly fact specific and controversial. In analysing whether a particular communication is not subject to the general prohibitions against "pre-approval promotion", the FDA will consider whether the communication: (1) is provided by scientific or medical personnel, free from commercial influence; (2) the information is truthful, balanced, and not misleading; and (3) the information is provided in response to an unsolicited request by a healthcare professional. While evidence that pre-approval information was provided at a scientific meeting or through a third party may support the case that a particular communication was not intended to be promotional, such evidence is not in and of itself dispositive to the analysis. The FDA will look to the degree of control and influence that a manufacturer has over a particular medical or scientific meeting to determine whether the pre-approval information can be "imputed" to a manufacturer. In a case where a manufacturer has significant control over the funding, content, or selection of attendees at a scientific meeting, the FDA will apply the same rules to product-specific information discussed at the meeting as it would apply to employees of the manufacturer.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Information on medicines that have not been approved by the FDA may be published so long as the publication is for the *bona fide* purpose of disseminating scientific information or findings. *See* 21 C.F.R. §312.7. Information on unapproved medicines may not be published for promotional or marketing purposes. *See* question 2.1 above.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

*See* questions 2.1 and 2.2 above. While such press releases may disseminate new scientific findings and developments to the scientific community and investors, companies must scrupulously

avoid suggesting in such releases that the product is approved or has been proven to be safe and effective, and they generally should not be distributed in a promotional setting, such as further distribution by company sales personnel. In general, a press release in the mainstream media is more likely to be seen as promotional. Investor communications are given more leeway (and are generally subject to Securities and Exchange Commission rather than FDA jurisdiction), although such communications should also be balanced and objective in reporting information, and refrain from stating safety or effectiveness. Further dissemination of an investor release in non-financial communications may be seen as promotional.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Manufacturers may send information to health professionals about medicines that have not been approved by the FDA in very limited circumstances in which the information is distributed for scientific and not promotional purposes, and generally when the information has been solicited by the health professional rather than cued by manufacturer personnel. Very limited communication of pipeline information – without claims regarding safety or effectiveness and clear caveats regarding unapproved status – are generally also low risk. *See* questions 2.1 and 2.2 above.

The FDA also permits "coming soon" advertisements within six months of the projected approval date; however, such advertisements may state only the proprietary and established name for the product without any information regarding the indication. Such advertisements are not permitted for products bearing a "black box" safety warning, and should not be used if the company is also engaging in disease state advertisements in the same preapproval period. *See* question 3.7 below.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

This has not had an impact in the U.S., although there are extensive requirements in the U.S. governing communications to physicians and patients regarding unapproved drugs in relation to expanded access programmes, including compassionate use. Such communications must generally adhere to the same rules that apply to other clinical trial-related communications with study subjects, and should not be promotional in tone or intent. Various enforcement actions have focused on the use of clinical trials for purposes of "seeding" future prescribing by physicians. Moreover, manufacturers generally may not require payment for investigational drugs, although there are mechanisms for seeking FDA approval to obtain "cost recovery" with no profit from study subjects. This is rarely done given the burdensome process for obtaining such approval. *See* question 2.1 above for a discussion of the dissemination of information regarding unapproved medicines to payor audiences.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

Sending information on an unapproved drug to third parties for such purposes could be construed as commercialising the drug, which is not allowed under FDA regulations, although such submissions do occur with some frequency, typically with numerous caveats and disclaimers to prevent a suggestion that the product is being promoted as safe and effective. However, if such third parties are payors – i.e., sophisticated parties making coverage and reimbursement decisions for a covered population, more extensive communications are permitted. *See* question 2.1 above. Such information may also be shared in response to *bona fide* unsolicited requests by government or private insurers, assuming the information is truthful, not misleading and balanced.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

While pre-approval market research is generally permitted under appropriate consulting arrangements, the FDA and other government authorities will scrutinise such research activities where health professionals are receiving compensation or if the number of healthcare professionals surveyed is excessive in relation to the market research need. Payments made to healthcare professionals to induce them to prescribe a manufacturer's products are prohibited under U.S. law. Consulting arrangements with such professionals must be for *bona fide* services, in writing, at a fair market value, and not intended to influence their prescribing decisions. An excessive audience for such research may indicate pre-approval "seeding" promotion rather than legitimate market research.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

The FDA's approach to regulation of advertising is based on its view that a manufacturer must present truthful, non-misleading information that adequately balances a prescription drug product's benefits and risks to the intended audience. U.S. law also requires that a manufacturer provide its consumers with adequate directions for the intended use of its prescription drug products. Therefore, while the requirements for both consumer-directed and healthcare professional-directed advertising are generally the same under U.S. law, the FDA will closely scrutinise whether the content is presented in terms that the intended audience can understand, and the FDA has developed special guidance addressing the application of regulatory requirements to consumer-directed broadcast advertising, communications in social media, and other fora.

Advertising for prescription drugs is subject to requirements under the disclosure of risk and other information. An ad for a prescription drug must include, in addition to the product's established name and quantitative composition, a "true statement" of information in brief summary "relating to side effects, contraindications and

effectiveness" of the product with respect to the use or uses that the message promotes. 21 U.S.C. 352(n); 21 CFR Part 202. FDA regulations also specify that, among other things, the statutory requirement of a "true statement" is not satisfied if an ad for a prescription drug product is false or misleading with respect to side effects, contraindications or effectiveness or if it fails to reveal material facts about "consequences that may result from the use of the drug as recommended or suggested in the advertisement". 21 CFR 202.1(e)(5).

FDA regulations specify that ads must present a fair balance between information relating to risks and benefits, which is achieved when the treatment of risk and benefit information in a promotional piece is comparably thorough and complete throughout the piece. 21 CFR 202.1(e)(5)(ii). The regulations identify 20 types of advertising communications that the FDA considers "false, lacking in fair balance, or otherwise misleading". 21 CFR 202.1(e)(6). These include, for example, representations or suggestions that a drug is more effective or safer than has been demonstrated by substantial evidence. The regulations also identify 13 additional types of advertising communications that "may be false, lacking in fair balance, or otherwise misleading". 21 CFR 202.1(e)(7). These include, for example, advertising communications that fail to "present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug". 21 CFR 202.1(e)(7)(viii).

In addition to specific requirements set forth in statutes and regulations, the FDA issued a draft guidance document setting forth its expectations for communication of risk information for prescription drugs and devices. *See* FDA. Draft Guidance for Industry: Presenting Risk Communication in Prescription Pharmaceutical and Medical Device Promotion (May 2009). While the guidance is not binding on the FDA, and does not replace the statutory and regulatory requirements, it is an important reflection of the Agency's current thinking on this topic.

Finally, recent legislative and regulatory proposals in the U.S. aim to curb the rising price of prescription medicines in part by proposing that manufacturers be required to be more transparent about the list prices of their products. Under one proposal issued by the Centers for Medicare and Medicaid Services (CMS) in Fall of 2018, regulators would require pharmaceutical companies to disclose their wholesale acquisition cost price for drugs in direct-to-consumer advertisements. The proposal would only pertain to drugs covered by the U.S. Medicare and Medicaid programmes and is part of a larger "blueprint" released by the Trump Administration to address prescription drug costs. The proposal has raised controversy, and some prominent industry groups, such as the Pharmaceutical Research and Manufacturers of America, have raised concerns that requiring companies to include CMS's pricing information without more context could have the effect of discouraging patients from seeking medical care. Further, an important legal question remains as to whether CMS can require companies to communicate information about their products in the manner proposed without running afoul of commercial-free speech protections. Companies with commercial products in the U.S. should continue to follow these developments closely, including to see if CMS ultimately adopts the proposed rule and whether it becomes the subject of industry challenge.

### 3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Advertisements generally must adhere to the terms of approved labelling, including consistency with respect to indication, dosing, mechanism of action, endpoints, and other aspects of labelling. However, it is possible to make certain claims relating to or expanding upon aspects of approved labelling if such claims are properly substantiated. As noted earlier, the FDA clarified in 2018 that it would permit companies to make claims consistent with the FDA-approved labelling of an approved drug product under certain conditions set forth in the guidance.

### 3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

While healthcare professionals may provide endorsements in promotional materials, the claims made by the endorser are treated as claims by the manufacturer, and thus are subject to the same rules. Thus, the statements made by the endorser should be consistent with approved labelling, truthful and not misleading, balanced, and generally representative of the experience of the average physician, unless otherwise clearly stated. A mere disclaimer is generally insufficient. Endorsers who act on behalf of a company may be subject to enforcement by the FDA, in addition to enforcement against the manufacturer. Ensuring transparency in advertising (including social media) with respect to the relationship between the physician endorser and the manufacturer can be particularly important.

### 3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

It has generally been the FDA's position that any advertising claim that represents or suggests that one drug is safer or more efficacious than another drug must generally be supported by substantial evidence or substantial clinical experience. *See* 21 C.F.R. §202.1(e)(6)(ii). Substantial evidence of safety and efficacy generally consists of at least one, and typically two or more, adequate and well-controlled clinical investigations comparing the products in a matter consistent with, and supportive of, the comparative claims. *See id*. at §202.1(e)(4)(ii). As noted earlier, the FDA's recent guidance on consistency with labelling and communications with payors provides companies with an ability to communicate some comparative safety and efficacy information where it is either consistent with the approved FDA labelling and substantiated by substantial evidence or, in the case of economic information provided to payors, substantiated by competent and reliable scientific evidence.

### 3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Prescription drug advertisements may not be false or misleading, and may not otherwise misbrand the product. *See* 21 C.F.R. §202.1(e)(6). Under FDA regulations, a comparator advertisement is false or misleading if it: "[c]ontains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience". *Id*. at §202.1(e)(6)(ii). Such an advertisement may also suggest uses that are not approved for the approved product, or present a false or misleading comparison. There is no reason *per se* why a company's brand name cannot be used in such a comparison.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

Scientific papers and other clinical information provided to doctors must meet the requirements of the FDCA. Scientific information that is provided as part of a prescription drug product promotion must generally be consistent with the product's FDA-approved label, and not untruthful or misleading. Therefore, manufacturers are limited in their ability to provide doctors with scientific or clinical information about unapproved new drugs or unapproved uses of approved drugs. *See* question 2.1. The FDA has taken the position that manufacturers may, under certain circumstances, provide healthcare professionals with information about unapproved uses of approved drugs in certain non-promotional contexts.

However, the FDA has provided in guidance documents that are reprints of scientific journal articles which discussed unapproved uses of approved products may lawfully be distributed in a non-promotional manner if certain criteria are met. These criteria generally relate to the credibility and independence of the publication, the truthfulness of the information, and the potential risk posed to patients and consumers who could rely on that information. While the guidance does not replace the requirements set forth under statutes or FDA regulations, it is a useful guide on the Agency's current thinking on this topic. *See,* FDA. Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices (February 2014) available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf. Another guidance addresses the dissemination of risk information that may be inconsistent with approved labelling. Guidance for Industry: Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products – Recommended Practices (June 2014) available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm400104.pdf.

Again, as noted, the FDA's traditional distinction between promotion and scientific exchange, and its ability to regulate truthful and non-misleading unapproved use information, has been called into question by recent First Amendment case law, and companies are currently exploring more aggressive forms of truthful and non-misleading off-label use communications than those contemplated under these and other FDA guidance documents.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

FDA regulations permit "teaser" advertisements as long as they relate to a drug which has been approved for marketing by the FDA. For example, FDA regulations allow the use of "reminder" advertisements (which only mention the name of the drug and not its use) and "help-seeking" advertisements (which encourage individuals with a particular condition to see a doctor without mentioning a specific product). *See* 21 C.F.R. §202.1(e). For an unapproved product, within certain limitations the FDA has permitted the use of either "Institutional Promotion" or "Coming Soon Promotion". With an "Institutional Promotion" advertisement, the manufacturer may state the drug company name and the area in which it is conducting research, but not the proprietary or established drug name. In "Coming Soon" advertisements, the manufacturer may state the drug name, but not the area in which the company is conducting research. Such options are not available for drugs bearing "black box" safety warnings.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

In general, if a product is promoted in an unapproved combination, claims about the safety or effectiveness of the combination use are treated like any other off-label product claim and subject to the same rules as single product off-label promotion noted in the responses above. The FDA may consider the combination product use a new use for each of the products being promoted in combination. Combination product claims will be regulated under the rules which apply to each of the product categories. So for example, if one product is a prescription drug and a second product promoted in combination with that product is a diagnostic test, the FDA can apply the standards for prescription drug approval and promotion to the claims made about the drug to the drug and those governing medical devices or laboratory tests to the test. In order for a company to lawfully promote two products in combination, the manufacturers of each product would need approval from the FDA for the combination intended use – the labelling of each product would generally need to reference the other and there would need to be substantial clinical evidence presented to the FDA and included in the approved labelling to substantiate the safety and effectiveness of the combination use. As noted, non-promotional communications – such as scientific exchange communications through which scientific journal reprints which report on the results of studies or real world use of combination uses (for example, in oncology) may be disseminated – may be permitted in compliance with FDA guidance.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Prescription drug sampling is a highly regulated practice in the U.S., particularly where the drug in question has serious potential for abuse, misuse, or serious side-effects. Drug samples may be distributed to heathcare professionals licensed to prescribe the sampled drug under the Prescription Drug Marketing Act and implementing regulations. FDA regulations allow samples to be distributed by: (1) mail or common carrier; or (2) direct delivery by a representative or detailer. *See* 21 C.F.R. §§203.30, 203.31. Under either form of distribution, the licensed practitioner must execute a written request and a written receipt. *Id*. When distribution occurs through a representative, the manufacture must conduct, at least annually, a physical inventory of all drug samples in the possession of each representative. *Id*. at §202.31(d). The manufacturer must also maintain a list of all representatives who distribute samples and

the sites where those samples are stored. *Id*. at §202.31(e). Drug samples may not be sold, purchased, or traded. *See* 21 U.S.C. §353(c)(1). Similarly, drug samples cannot be provided to healthcare professionals with the understanding that those professionals will seek reimbursement for the samples from public or private insurance schemes. However, under certain conditions, drug samples may be donated to a charitable institution. *See* 21 C.F.R. §203.39. Additional restrictions apply to the dissemination of any product that is a controlled substance. In certain circumstances, free drug products, not labelled as samples, may also be provided to healthcare professionals as part of patient assistance programmes ensuring continuity of care. However, the provision of such free product should be evaluated carefully under fraud and abuse and pricing laws.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Under the U.S. Anti-Kickback Statute, it is generally unlawful to offer any type of remuneration directly or indirectly to any person or entity in a position to purchase, lease, order or prescribe (or influence the purchase, lease, order or supply) a service or item reimbursed by a state or federal healthcare programme if even one purpose of the remuneration is to increase utilisation of products or services reimbursed under those schemes. *See* 42 U.S.C. §1320a-7b(b). Safe harbours apply to, among other types of payments or discounts, *bona fide* personal services, such as consulting arrangements undertaken for fair market value compensation.

Moreover, under the U.S. Foreign Corrupt Practices Act (FCPA), manufacturers who are issuers of shares on U.S. stock exchanges may not offer any type of remuneration directly or indirectly to any ex-U.S. government official with the intent of improperly influencing an official decision to obtain or retain business or gain an unfair advantage. *See* 15 U.S.C. §78dd-1. U.S. authorities have interpreted these statutes very broadly. Under the FCPA, "government official" includes employees of government-run healthcare institutions or businesses over which foreign governments have control. Under both the Anti-Kickback Statute and the FCPA, "remuneration" is interpreted very broadly, and there is generally no *de minimis* exception. Pharmaceutical manufacturers must, therefore, carefully scrutinise sales and marketing practices involving gifts, donations or other forms of remuneration that may be given to medical professionals and/or facilities.

Pharmaceutical manufacturers doing business in the U.S. should be familiar with the "guidelines" regarding relationships with physicians and other persons or entities in a position to make or influence referrals published by the following three entities: (i) The PhRMA Code on Interactions with Healthcare Professionals, available online at http://www.phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals; (ii) The HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) available online at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf; and (iii) The AMA Guidelines on Gifts to Physicians from Industry, available online at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/about-ethics-group/ethics-resource-center/educational-resources/guidelines-gifts-physicians.page?. While the PhRMA and AMA codes are voluntary, and do not take the place of statutory or regulatory provisions, U.S. authorities have encouraged manufacturers to comply. As of January 2009, PhRMA has prohibited its members from providing any item of any value that may given in exchange for prescribing products or a promise to continue prescribing products, without consideration of their value. Even items intended for the personal benefit of the physician, including cash or cash equivalents, are inappropriate (except as compensation for *bona fide* services). So, for example, gift certificates, tickets to a sporting event, artwork, music, and floral arrangements would be prohibited under all three sets of guidelines.

Note that in many cases the U.S. Physician Payment Sunshine Act requires reporting and public posting on a government "Open Payments" website, of payments or other transfers of value to prescribers and teaching hospitals. Certain states also prohibit gifts or transfers of value to healthcare providers, and institutional policies may also limit such activities.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

Yes, it is possible to give donations and other items of value to healthcare organisations for legitimate charitable or educational purposes under certain limited circumstances. The Anti-Kickback Statute addressed above in question 4.2 applies to any remunerative relationship between the manufacturer and a person or entity in a position to generate federal healthcare programme business for the manufacturer. Such persons or entities would also include institutions such as hospitals or clinics. The OIG takes the position that goods and services provided by a manufacturer to a healthcare professional or institution that reduce or eliminate an expense the provider would otherwise have incurred (e.g., a business operational or overhead expense) implicates the Anti-Kickback statute if the arrangement is tied to the generation of federal healthcare programme business. Therefore, manufacturers must refrain from providing any form of remuneration to a healthcare professional for operational or overhead expenses. It is possible to provide grants for *bona fide* research or other scientific/medical activities, but particular processes should be in place to ensure that decisions are made by medical affairs personnel, the amount is commensurate with the proposed research or other activity, and the grant is not for a promotional or other purpose that could be construed as an attempt to induce claims for the manufacturer's products. Similar considerations apply to charitable donations made to institutions that are in a position to purchase, prescribe, use, or recommend the donor's products. Donations may also implicate the FCPA where the donations are given with the intent to influence the official acts of foreign government officials, including employees of government-run medical institutions. No specific monetary limits apply to such gifts or donations, provided the gift or donation is otherwise lawful as outlined above. Note that such transfers of value, if given to a teaching hospital, may be reportable under the Sunshine Act.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

Under U.S. law, it is generally unlawful for a manufacturer to provide doctors with any item of value which was intended to lead to changes in prescribing patterns in favour of that manufacturer's products or services. U.S. law also limits the relationships a manufacturer may have with non-doctor third-parties, such as pharmacies, insurers, consumers, and other entities, which are

intended to refer patients or healthcare professionals to a manufacturer's products or services.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

To encourage price competition, the Federal Anti-Kickback statute contains both a statutory exception and regulatory safe harbour for discounts. *See* 42 U.S.C. §1320a-7b(b)(3)(A); 42 C.F.R. §1001.952(h). Both the statutory exception and regulatory safe harbour contain specific conditions that must be met. For example, all discounts must be disclosed and properly reported. Additionally, to qualify under the discount safe harbour, discounts must be in the form of a price reduction and must be given at the time of the sale (under certain circumstances the discount may be set at the time of the sale). *See* 42 C.F.R. §1001.952(h). Notably, the regulatory safe harbour provides that the term "discount" does not include: (i) cash payment or cash equivalents; (ii) supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same federal healthcare programme using the same methodology and the reduced charge is fully disclosed to the federal healthcare programme and accurately reflected where appropriate to this reimbursement methodology; (iii) a reduction in price applicable to one payer but not to Medicare or a State healthcare programme; (iv) routine reduction or waiver of any coinsurance or deductible amount owed by a programme beneficiary; (v) warranties; (vi) services provided in accordance with a personal or management services contract; or (vii) any other remuneration, in cash or kind, not explicitly described in the regulation. *See* 42 C.F.R. §1001.952(h).

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Under U.S. law, no gift or payment should be made contingent on the purchase of medicinal products that is reimbursable under U.S. government healthcare programmes. Similar limitations apply under certain state laws.

Although it may be possible to bundle medicines and other value or services provided to physicians in certain circumstances, particularly if the value or services are necessary for safe use of the medication, such value or services should not create an inducement for use of the product, and bundling activities may have an impact on drug pricing for government reporting purposes. Such factors must be carefully scrutinised in each specific arrangement.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Yes. Such programmes are not typically used for individual patients who are prescribed prescription drugs, but given the high cost of certain treatments, such as gene therapies, increasingly we will see a guaranty of retreatment if an initial treatment fails. Moreover, as noted, such schemes are a definite focus in the context of manufacturer-payer agreements providing financial incentives based on the overall outcomes within the insured patient population. In addition to the difficulties of accessing sufficient data to facilitate such value-based arrangements, they pose a wide range of fraud and abuse, off-label promotion, and price reporting complexities. In the over-the-counter space, such refund schemes are much more common, and are similar to the money-back guarantees seen for other consumer products. Such provisions are largely governed by Federal Trade Commission and state rules.

Safe harbour analysis is critical for any proposed warranty scheme involving a product for which federal healthcare programme reimbursement is available; warranties can be considered value transfers which implicate the Anti-Kickback Statute. Importantly, there is a "warranty" safe harbour in the Anti-Kickback law that excludes certain warranty payments from the definition of "remuneration" under the statute. *See* 42 C.F.R. §1001.952(g). The definition of warranty in the warranty safe harbour incorporates the Federal Trade Commission's definition of warranty which includes "any undertaking in writing...to refund, repair, replace, or take other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking". 15 U.S.C. §2301(6)(B). The safe harbour warranty only protects warranties on "items", so a warranty on a combination of items and services does not technically qualify for protection. Safe harbour protection is available as long as the buyer complies with the standards of 42 C.F.R. §1001.952(g)(1)-(2) and the manufacturer or supplier complies with the following standards of 42 C.F.R. §1001.952(g)(3)-(4):

- The manufacturer or supplier must comply with either of the following two standards: (i) the manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section; and (ii) where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
- The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

Safe harbour protection is highly fact-specific and must be analysed based on the particulars of the specific warranty offer/arrangement.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

It is permissible for manufacturers to support the education of the medical community through sponsoring continuing medical education (CME), however, these relationships must be consistent with U.S. federal healthcare laws and applicable professional society guidelines. For example, if pharmaceutical manufacturers provide financial support for medical conferences or meetings other than their own, control over the content and faculty of the meeting or conference must generally remain with the organisers. The FDA and OIG have set forth their expectations for manufacturer-supported CME in guidance documents. In particular, these authorities are concerned with

financial relationships between manufacturers and CME providers that could transform otherwise beneficial, independent medical information into promotional vehicles for manufacturer products (including unapproved uses of those products). *See*, e.g. FDA. Guidance for Industry. Industry-Supported Scientific and Educational Activities (December 2007) available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.pdf; OIG. OIG Compliance Program Guidance for Pharmaceutical Manufacturers (May 2003) available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf; PhRMA Code on Interactions with Healthcare Professionals, available online at http://www.phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals. Support for medical education must also be structured to comply with the Anti-Kickback Statute, the PhRMA Code, the FCPA and other applicable guidelines, since such support may result in an item of value being provided to healthcare professionals.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

As noted in response to question 4.2, there is both a domestic and international framework prohibiting kickbacks or other corrupt payments to healthcare professionals and organisations. Within the U.S., subject to certain safe harbours, the U.S. Anti-Kickback Statute prohibits offering any type of remuneration directly or indirectly to any person or entity in a position to purchase, lease, order or prescribe (or influence the purchase, lease, order or supply) a service or item reimbursed by a state or federal healthcare programme if even one purpose of the remuneration is to increase utilisation of products or services reimbursed under those schemes. *See* 42 U.S.C. §1320a-7b(b). Internationally, under the FCPA, manufacturers who are issuers of shares on U.S. stock exchanges may not offer any type of remuneration directly or indirectly to any ex-U.S. government official with the intent of improperly influencing an official decision to obtain or retain business or gain an unfair advantage. *See* 15 U.S.C. §78dd-1. The Anti-Kickback Statute is enforced by the Department of Justice and Office of Inspector General of the Department of Health and Human Services, and the FCPA is enforced by the Department of Justice and Securities and Exchange Commission. There is an increasing enforcement focus on investigating patterns of kickbacks and corruption that involve both U.S. and ex-U.S. healthcare practitioners and institutions, particularly those with a government institution nexus. For example, Department of Justice settlements with Olympus Corporation of the Americas stemmed from an investigation that involved both domestic kickback and Latin American bribery allegations. *See* https://www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Providing "hospitality", such as meals and social functions to health professionals would be governed by the aforementioned federal Anti-Kickback Statute as well as state laws. In cases where hospitality is provided to health professionals employed by ex-U.S. government institutions, the U.S. FCPA may also be implicated. The guidelines set by OIG as well as PhRMA, the AMA and other professional organisations discussed above in question 4.2 would also be relevant. For example, under the PhRMA Code a company may hold informational presentations that serve a valid scientific purpose and provide a "modest meal" by local standards. The company cannot, however, provide entertainment or a recreational outing and cannot pay for a spouse's or guest's meal. The AMA guidelines provide that subsidies for hospitality should not be accepted outside of modest meals or incidental social events held as part of a conference or meeting. *See also* question 5.2.

The choice of country would not be a factor in the analysis under the Anti-Kickback Statute or under U.S.-based professional guidelines. Further, an ex-U.S. event could raise risks under the FCPA if government officials were invited to participate or attend the event. It is generally best practice to require approval by the local affiliate where the hospitality takes place, as well as the affiliate where the payment is originating, in order to ensure compliance with local requirements and fair market value. Finally, meal costs and other hospitality – even when permissible – must be tracked and reported under applicable transparency laws.

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

As with the provision of hospitality, travel and honorarium payments are items of value that implicate the Anti-Kickback Statute, FCPA, certain state laws, and the professional guidelines noted above. In general, a manufacturer's financial support may be appropriate if: (i) the subsidy is sent directly to the conference sponsor; (ii) the sponsor uses the subsidy to create an overall reduction in conference registration fees for all attendees; and (iii) the physician does not receive the subsidy directly. Non-faculty professionals should not be paid for the costs of travel, lodging, or any other personal expenses. A manufacturer may, however, offer financial support to sponsors for modest meals or receptions so long as the meals and receptions are provided for all attendees. Funding should not, however, be offered to pay for the physician's time associated with attending the conference and no direct or indirect payments (including reimbursements made directly to attendees or to their travel agencies) may be paid with the intention of influencing their prescribing behaviour or otherwise referring them to a manufacturer's products or services. Finally, as noted earlier, lawful payments or reimbursements must be tracked and reported under transparency laws.

These limitations should be distinguished from *bona fide* personal services arrangements such as compensation for investigators to attend investigator or consultant meetings in a manner consistent with the terms for such arrangements under the Anti-Kickback Statute, where the payments are made at a fair market value for services rendered. *See* the answer to question 5.4, below. Note also that transparency reporting requirements may apply to such payments.

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

In instances where such meetings do not meet FDA and OIG's indicia for independence (*see* the guidance documents discussed in question 4.8), U.S. authorities will generally take the position that a supporting manufacturer is responsible for the content presented at such meetings, as well as any items of value offered to attendees.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

Yes. As noted, U.S. regulations create a safe harbour to the Anti-Kickback Statute for "personal services", provided all of the requirements of the safe harbour are met. *See* 42 C.F.R. §1001.952(d). Manufacturers may enter into consulting agreements with physicians so long as the compensation reflects a fair market, a commercially reasonable value, there is a legitimate need for the services, and the arrangement does not take into account the past, present, or future prescribing or purchasing potential. As outlined in government regulations, as well as professional society guidelines, there are several factors that are relevant in identifying the existence of a *bona fide* consulting arrangement: (i) the agreement is in writing and specifies the nature of the services to be provided and the basis for the payment of those services; (ii) a legitimate need for the services has been identified (and documented) in advance of the request for services and entering into arrangements with prospective consultants; (iii) the criteria for selecting the consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to decide if the consultant meets the criteria; (iv) the number of consultants retained is not greater than the number reasonably necessary to achieve the desired purpose; (v) the company maintains records of the services provided and makes appropriate use of the services provided; (vi) the venue and circumstances of any meeting with consultants is conducive to the consulting services provided and activities related to the services constitute the primary focus of the meeting, with any social or entertainment events clearly subordinate in terms of time and emphasis; and (vii) no payments are made for the consultant's spouse or significant other to attend the meeting. A similar analysis should be conducted to limit a manufacturer's exposure to liability under the FCPA, where the personal services are between a manufacturer and a government official or employee (such as a clinical investigator who is also employed by a government-run hospital).

A failure to comply with these requirements can result in severe civil and criminal consequences for a U.S. manufacturer, as well as responsible corporate officials. This is especially true where advertising and promotion issues converge with payment arrangements with healthcare professionals. Inappropriate advisory board activities, such as holding numerous advisory boards that were clearly for the purpose of disseminating off-label information and seeding prescribing as opposed to a genuine goal of receiving advice, have formed the basis for government enforcement resulting in major settlements.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

While it is possible to compensate doctors to participate as investigators in clinical trials, the compensation must comply with the FDA regulations governing clinical research. Such studies should have a clear scientific/medical rationale, and should not constitute a "seeding" effort to market the product to physicians. Payments must also conform to the requirements under the Anti-Kickback Statute and, where applicable, the FCPA.

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

Yes, if the market research is *bona fide* research (i.e., designed to achieve a legitimate commercial research question) and the payments are fair market value for the time required of the healthcare professionals. An excessive audience for such research may indicate pre-approval "seeding" promotion or kickbacks rather than legitimate market research.

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, non-prescription or OTC drugs may be advertised to the general public. As discussed above in question 1.1, advertisements for monograph non-prescription drugs are primarily regulated by the FTC, not the FDA. U.S. law prohibits the dissemination of non-prescription drug advertisements that are deceptive or otherwise misleading. *See* 15 U.S.C. §52. This prohibition applies to non-prescription drug advertisements. A "false advertisement" is defined as an advertisement "which is misleading in a material respect". *Id*. at §55. In determining whether an advertisement is misleading, several factors will be considered, including the representations made or suggested by word, design, device, or sound and any material facts omitted.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

Yes, DTC advertising is also allowed for prescription drugs. Under FDA regulations, "advertisements" subject to the FDCA fall into two categories: print advertisements; and broadcast advertisements. Print advertisements include "advertisements in published journals, magazines, other periodicals, and newspapers...". Broadcast advertisements include "advertisements broadcast through media such as radio, television, and telephone communication systems". 21 C.F.R. §202.1(l)(1). Both types of advertisements may not be false or misleading and must present a fair balance between the efficacy of a drug and its risks. *Id*. at §202.1. Additional FDA requirements differ slightly depending on the type of advertisement.

**Print Advertisements**

The FDCA and FDA regulations require that all prescription drug advertisements discussing the effectiveness or indications of the drug

must include a brief summary of side effects, contraindications, and effectiveness (known as the "brief summary" requirement). *See* 21 U.S.C. §352(n); 21 C.F.R. §202.1(e). This brief statement must include all risk information contained in the approved labelling, including all side effects, contraindications, warnings, precautions, and adverse reactions. *See* 21 C.F.R. §202.1(e)(3)(iii).

To satisfy the brief summary requirement, manufacturers will usually reprint the relevant sections of the package insert. The package insert is directed at healthcare providers and may be difficult for consumers to understand. As a result, the FDA has suggested that manufacturers use consumer-friendly language on contraindications, warnings, major precautions, and frequently occurring side effects in print advertisements directed at consumers. Two types of advertisements are not subject to the brief summary requirement:

- Reminder Advertisements.
- Help-Seeking Advertisements.

**Broadcast Advertisements**

While broadcast advertisements are subject to several technical requirements that differ from those of print advertisements, the FDA applies the same guiding regulatory principles to both types of ads, when determining whether a particular ad adequately communicates risks and benefits to consumers. *See* question 3.1 above.

A broadcast advertisement must include a statement of the most important risk information (known as the "major statement" requirement). A broadcast advertisement must also either include a brief summary, as discussed above, or make "adequate provision... for the dissemination of the approved or permitted package labelling in connection with the broadcast presentation" (known as the "adequate provision" requirement). 21 C.F.R. §202.1(e)(1). In a guidance, the FDA has indicated that a manufacturer can satisfy the adequate provision requirement by:

- providing a toll-free phone number for consumers to call for the approved labelling;
- referencing a printed advertisement or brochure that can be accessed with limited technology;
- providing reference to an internet website that contains the requisite labelling; and
- advising consumers to ask doctors or pharmacists for more information.

### 6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

While prescription drug advertisements are allowed in the U.S., a manufacturer may use "help-seeking" or disease-oriented advertisements focused on raising awareness of a particular condition and not addressing a specific brand. Such advertisements should not be framed so narrowly as to constitute *de facto* advertising for a specific product, and should be perceptually distinct from branded advertising.

### 6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

There is no prohibition on such press releases so long as the drug has received marketing approval from the FDA and the press release is otherwise compliant. Because such press releases may be regulated as promotional materials, the information they contain must be consistent with the drug's FDA-approved label and otherwise meet the requirements set forth for promotional materials under U.S. law. If the product is not approved, the information should make clear that the product is not approved by the FDA and should not include safety or effectiveness claims. In some narrow circumstances, a manufacturer may distribute material, new scientific findings to the lay media prior to approval. *See* questions 2.1 and 2.2 above. Note that press releases relating to product developments may also be scrutinised under applicable securities laws. The FDA and the Securities and Exchange Commission frequently coordinate on matters involving prescription drug communications.

### 6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Although such materials are generally not considered promotional materials for specific products, in certain circumstances they may be used in that manner. There are no specific restrictions on product descriptions and research initiatives, other than the prohibition against the general prohibition on false and misleading promotion, including unlawful *promotion* of unapproved new drugs or unapproved uses of approved drugs. Note that laws governing the accuracy and transparency of securities disclosures may apply, and the FDA and the U.S. Securities and Exchange Commission frequently coordinate on matters involving prescription drug communications.

### 6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

Prescription drug and medical device manufacturers may provide charitable funding to patient support groups. Such funding decisions should generally be made through a formal grant process. Funding to patient organisations may implicate the Anti-Kickback Statute if such groups include prescribers or the organisations have the ability to refer patients to physicians or otherwise influence prescribing. Notably, the OIG has published guidance and several advisory opinions which provide the Agency's views as to when the Anti-Kickback Statute may be implicated through patient organisation support. The FCPA, as well as state and federal tax laws, may also be implicated in certain scenarios. Certain state laws require manufacturers to publicly disclose funding to such groups to state officials. Further, professional and industry guidelines (such as the AMA and PhRMA Codes discussed earlier) may require individual organisations and medical professionals to make public disclosures on a case-by-case basis. Note that the U.S. Pharmaceutical Research and Manufacturers of America maintains industry principles on interactions with patient groups. http://www.phrma.org/sites/default/files/pdf/phrma_principles_paper_20120919_final.pdf. Finally, industry funding of third-party organisations which provide financial assistance to patients has come under increased scrutiny in the U.S. in recent years out of a concern by regulators that such funding can steer patients to the funding company's products.

### 6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Within limits, items may be provided to patients via their physicians if the items are designed primarily for the education of patients, are

not of substantial value (generally $100 or less) and do not have value to the healthcare professional outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas an iPad® may have independent value to a healthcare professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate. Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate. Moreover, certain items may be provided directly to patients if they are *de minimis* in value, generally relate to the medical treatment, and not intended as an inducement to seek a particular product. An example would be a very inexpensive container that permits the patient to maintain the proper temperature of a product.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

Yes. Registration is required at clinicaltrials.gov for trials that meet the definition of an "applicable clinical trial" under relevant legislation. *See* https://clinicaltrials.gov/ct2/manage-recs/fdaaa. Applicable clinical trials include controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to FDA regulation, and generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

- The trial has one or more sites in the United States.
- The trial is conducted under an FDA investigational new drug application or investigational device exemption.
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research.

Extensive information on the parameters for, and ultimately the results of, the clinical trial must be provided, and the National Institutes of Health recently finalised rules expanding the results information requirement very substantially. *See* https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

Yes. The Physician Payments Sunshine Act requires "applicable manufacturers" of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program (CHIP), to report annually to the Centers for Medicare and Medicaid Services (CMS), in an electronic format, certain payments or other transfers of value to "covered recipients" – physicians and teaching hospitals. Data collection and reporting began on August 1, 2013. Payment data is due to CMS each year by March 30, and must be posted on CMS's "Open Payments" website in June.

"Applicable manufacturer" is defined as an entity that operates in the U.S. and is "engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply . . . .". A "covered" product means that payment must be available under Medicare, Medicaid or (CHIP) and the product requires a prescription or premarket approval (devices). This includes products that are reimbursed separately or as part of a bundled payment. The Sunshine Act only requires applicable manufacturers to register with CMS and report payments to the agency if they have made reportable payments or transfers of value to "covered recipients" in the applicable calendar year.

The Sunshine Act applies to payments or transfers of value made by applicable manufacturers to "covered recipients", who are defined to include: (1) physicians; and (2) teaching hospitals. Physician includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorised to practice by the State in which they practice. Thus, the law applies to a physician who is licensed in the U.S., even if they maintain a licence or practice in a different country. This includes all physicians and fellows that have a current or active licence, regardless of whether they are enrolled with CMS or currently or actively seeing patients. Medical residents are not "covered recipients". Payments to prospective employee physicians (e.g., recruiting costs), including travel, lodging and meals, are also reportable. *Bona fide* employees of an applicable manufacturer that are U.S.-licensed physicians are also exempt from the definition of covered recipient.

Teaching hospitals are also covered recipients. CMS publishes a list of teaching hospitals once annually that will be available 90 days before the reporting year and will include tax identification numbers. CMS has clarified that hospitals not listed on the Open Payments teaching hospital list are not considered a teaching hospital covered recipient for purposes of Open Payments.

Applicable manufacturers must report to CMS "payments or other transfers of value" made to covered recipients, which the Sunshine Act broadly defines as "*anything* of value". This could include a medical journal reprint, travel and lodging, meals, research grants, and any other payments or transfers of value unless otherwise exempt or excluded. Two types of payment reporting apply: (1) general payments; and (2) research payments. The final regulations explain the specific types of information that manufacturers must report to CMS for each payment or transfer of value.

Certain payments or transfers of value are excluded from reporting under the Sunshine Act. These include certain "indirect payments" or transfers of value. CMS defined an "indirect payment" as a payment or transfer of value made by a manufacturer to a physician or teaching hospital *through a third party or intermediary*, in which the manufacturer "requires, instructs, directs or otherwise causes" the third party to provide payment or transfer of value, in whole or in part, to a physician or teaching hospital. In other words, "indirect payments…are made to an entity or individual (that is, a third party) to be passed through to a…" physician or teaching hospital. Although each payment arrangement must be carefully reviewed, the Sunshine Act does not require manufacturers to report indirect payments where the applicable manufacturer is "unaware" of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following year. Under the final regulations, a manufacturer is unaware of the identity of a covered

recipient if the manufacturer does not "know" the identity of the covered recipient. The definition of "know" provides that a person has actual knowledge of the information, acts in deliberate ignorance of the information, or acts in reckless disregard of the truth or falsity of the information.

In general, these requirements apply to foreign companies (including, in some cases, foreign affiliates that have a role in supporting U.S. products) who otherwise qualify as applicable manufacturers. Companies without approved or "covered" products subject to payment under government healthcare programmes, as outlined above, are not required to report under the Sunshine Act.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

As noted above, the Sunshine Act provides for posting of such transfers of value on the CMS Open Payments website. In general, these posting requirements apply to foreign companies (including, in some cases, foreign affiliates that have a role in supporting U.S. products) who otherwise qualify as applicable manufacturers. Companies without approved or "covered" products subject to coverage under government healthcare programmes, as outlined above, are not required to report under the Sunshine Act.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

While there are processes for physicians to review and dispute reported transfers of value directly with CMS (*see* https://www.cms.gov/OpenPayments/Program-Participants/Physicians-and-Teaching-Hospitals/Review-and-Dispute.html), and many companies have developed mechanisms for allowing physicians to review and reconcile payments prior to submission of Sunshine Act reports, if a transfer of value is accurate and otherwise required to be reported under the Sunshine Act, the physician may not refuse to permit such disclosure.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

The FDA generally takes a cautious approach to Internet-related advertising, attempting to apply traditional policies and concepts to such communications, with certain accommodations. The FDA has also developed certain draft and final guidance documents addressing aspects of Internet communications, including activities involving interactive media and when companies take on responsibility for content and must make submissions to the FDA, communications in character-limited settings such as Twitter, and correcting misinformation on the Internet. *See*: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf; http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401087.pdf; and http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401079.pdf.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

Given that prescription medicines may be lawfully promoted to patients in the U.S., no specific level of security is required, although such security may be useful in certain circumstances in order to clearly delineate information intended for healthcare professionals *versus* lay audiences (for example, by placing "pop-ups" or "roadblocks" on the relevant web pages). Some prescription drug websites require the healthcare professional to register while others have no security at all. Such a security requirement would factor in a regulator's overall analysis regarding the nature and purpose of the website, and the applicable rules for website content.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

While the rules in this area are not entirely clear, the FDA has promulgated draft guidance to help companies determine when they are responsible for user-generated content on sites in which they participate or link, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf. In many cases, the FDA has taken the position that such links incorporate the content of linked sites (e.g., relating to off-label uses), unless steps are taken to create a buffer (e.g., at a minimum, a click-through disclaimer) indicating that the user is leaving the promotional, company-sponsored site.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

There are no specific requirements governing what can be on the company website. Rather, the general requirements regarding promotion, scientific exchange, disclosures, and securities requirements apply, and many warning and untitled letters provide additional guidance on FDA areas of concern, particularly with respect to websites focusing on pipeline investigational products. The FDA has been active in sending untitled and Warning Letters to companies who appear to be promoting unapproved products on the web. Further, the FDA's "Bad Ad" Programme encourages physicians, patients, and competitor companies alike to inform the FDA of potentially violative advertising and marketing practices, which has driven many of the recent instances of FDA enforcement for web-based promotion over the past year. Independent of the promotion and advertising regulations, companies with ongoing Phase II and III clinical drug trials are required to place certain information about their policies supporting compassionate use and expanded access to investigational therapies on a public-facing website.

### 8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

As noted, while the FDA has generally tried to apply its general approach to drug promotion to the social media context, the FDA has developed certain draft and final guidance documents addressing aspects of such communications, including activities involving interactive media and when companies take on responsibility for content and must make submissions to the FDA, communications in character-limited settings such as Twitter, and correcting misinformation on the Internet. *See*, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401087.pdf and http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401079.pdf.

## 9 Developments in Pharmaceutical Advertising

### 9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

As noted earlier, the recognition by the FDA of the public health benefits of allowing companies to share truthful, non-misleading information about unapproved products or information about unapproved uses of approved products with payors under certain circumstances represents an important shift in regulatory policy and a rebalancing of regulatory interests in the U.S. Similarly, the issuance of guidance clarifying the boundaries of permissible communications "consistent with" (but not contained in) the FDA-approved labelling of drug products also presents an incremental but formal expansion of the scope of permissible manufacturer marketing and promotion practices. Finally, the attention on prescription drug prices, and the pharmaceutical industry's marketing of prescription drugs in general, has continued to capture the attention of regulators, legislators, and the public alike and is one of the few bipartisan political priorities emerging from the past year.

### 9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

In addition to the continued evolution of the First Amendment debate, we will continue to see a False Claims Act focus on enforcement relating to pharmaceutical manufacturer promotional practices more generally, particularly under Anti-Kickback Statute-based theories, and a focus on the connection between pharmaceutical promotion, pricing, and patient and reimbursement assistance programmes. Further, the FDA has been active in policing pre-approval promotion, promotion and marketing practices which appear to downplay safety risks (particularly in connection with REMS products), and promotion and marketing practices in the opioid products sector, which has become a significant bipartisan political priority and has also garnered the attention of state and federal legislators.

### 9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

As noted, a focus on pharmaceutical pricing has become particularly important, and prosecutors have responded by focusing heavily on aspects of pharmaceutical manufacturer programmes that allegedly unlawfully blunt the impact of pharmaceutical pricing on patients or deter the use of generic products. Market access programmes, particularly those which seek to lower copay costs for patients without passing on savings to the government and those which provide free and valuable services to physicians or other healthcare providers have also been a focus of enforcement attention over the past year. Promotional speaking activities and educational grant and sponsorship activities continue to be an area of scrutiny as well.

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# Venezuela

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## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The advertising of medicinal products is governed by the Medicines Law (2000), the Norms for Advertisement and Promotion of Pharmaceutical Products issued by the National Institute of Hygiene Rafael Rangel (INHRR). Also, the general rules against unfair competition established in the Antimonopoly Law (2014), which prohibit false and misleading advertising, are applicable. There are some self-regulatory norms issued by the Venezuelan Chamber of Medicines (CAVEME). As this is a trade association, such norms are documented in its Code of Conduct (2012) which has been harmonised with the Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). There is another set of self-regulatory norms issued by the Venezuelan Industrial Chamber of Pharmaceuticals (CIFAR), which is another trade association, documented in its Code of Conduct (2007). Each of the Codes of Conducts issued by CAVEME and CIFAR will be applicable only to the members of each trade association.

### 1.2 How is "advertising" defined?

The Medicines Law (2000) does not define the word advertising but defines the term "promotion" instead. This law established that the promotion of pharmaceutical products refers to all information and advertising activities carried out by manufacturers, distributors and dispensers. Instead, the term "advertising" is defined by the Norms for the Advertisement and Promotion of Pharmaceutical Products issued by INHRR. This rule establishes that advertising means any form of impersonal communication paid by a sponsor of a product that is conveyed to the public through mass media.

It is important to highlight that all promotions and advertisements must comply with certain principles. They must be: (a) informative; (b) educational; (c) truthful; (d) precise; (e) unequivocal; (f) current; (g) balanced; and (h) subject to testing.

### 1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

There are no legal requirements in this regard. However, the CAVEME Code of Conduct establishes that the pharmaceutical company must appoint an employee with enough knowledge and qualifications to oversee the approval of all promotional information, including advertising. Also, the person that manages the marketing authorisation process must be cognisant of the standards and regulations on the advertisement of drugs.

### 1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There are no explicit legal or code requirements for companies to establish Standard Operating Procedures (SOPs). However, the CAVEME Code of Conduct establishes that the company must train its prominent employees on the content of the Code, including the content regarding the promotion and advertisement of drugs.

### 1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

First, it is important to note that the promotion and advertisement of prescription drugs can only be targeted at healthcare professionals. However, over-the counter (OTC) products can be promoted and advertised to the general public.

In this sense, the dissemination of advertisement material of OTC drugs through mass media must be previously authorised by the health authorities. The sponsor pharmacist of the product or the regent pharmacist of the laboratory manufacturer or distributor of the product must file the corresponding authorisation before the Review Board of Pharmaceutical Products of the INHRR. The application to authorise the advertisement must include all the promotional materials and the Review Board must issue its decision regarding the authorisation within 15 working days.

### 1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

The Review Board of Pharmaceutical Products of the INHRR can

deny the authorisation, but once the advertisement is approved, it cannot stop its publication *ex officio*. However, third parties (including a competitor) are entitled to file complaints before the health authorities against the advertisement if it deems that such advertisement breaches the laws.

Furthermore, any third party can also file a complaint before the antitrust authorities and the consumer rights agency, when it deems that the advertisement has breached any of the laws enforced by said agencies. Hence, both of the authorities mentioned previously can stop the publication of the advertisement.

The decision to suspend the advertisement issued by any of the agencies mentioned above is subject to appeal.

**1. 7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The Medicines Law (2000) establishes that the promotion and advertisement of drugs that breaches the applicable legal framework is punished with fines of between 185 and 370 tax units. Please be aware that as of the date of drafting of this article, each tax unit is equal to US$ 0.01.

The responsibility for enforcement lies with the Ministry of Health and on the Review Board of Pharmaceutical Products of the INHRR. The Board, in case of verifying an infraction to legal regulations on promotion and advertisement, will recommend to the corresponding instance the application of sanctions that may be applicable.

There has not been a strict enforcement of the rules on the promotion and advertisement and there are no recent relevant cases in this regard.

On the other hand, competitors can take direct actions before the courts in relation to advertising infractions, provided that the claimant has standing to file such claim.

**1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?**

The competent authorities in this matter will only enforce the legal norms and regulations and do not take into consideration any self-regulatory standards. Hence, the health authorities will only investigate matters that are drawn to their attention either through the claim of a third party or due to an administrative procedure initiated by such authority. Whether the same matter is being assessed by a self-regulatory body is irrelevant.

On the other hand, the authorities do not take up matters based on adverse findings of any self-regulatory body, especially because the procedures before self-regulation bodies are usually confidential.

**1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?**

The Antimonopoly Law (2014) establishes that any third party who has suffered damages due to unfair competition practices, including the publication of false or misleading advertisement, has standing to file a claim before the antitrust authority. Moreover, the antitrust agency can initiate an administrative procedure *ex officio* to determine if the advertisement of a pharmaceutical product breached any antitrust regulations.

## 2 Providing Information Prior to Authorisation of Medicinal Product

**2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same regarding the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?**

Promotion and advertisement of a product that is not authorised for commercialisation is not allowed. However, there are no legal norms that specifically regulate the distribution of non-promotional information to healthcare professionals; the general principle is that a product cannot be mentioned in any forum or media until it has been approved.

The CAVEME Code of Conduct establishes that the diffusion of adequate and scientific information on a product in scientific media and fora is allowed. However, the discussion must be on either the treatment or the molecule, but the name of the product cannot be mentioned until it is approved.

On the other hand, the CAVEME Code of Conduct does not specifically limit (provided it is of scientific nature) the type of information that can be shared nor distinguish if the forum in which the information is shared is sponsored by the manufacturer or distributor of the product.

**2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?**

Promotional information cannot be published for unauthorised products. However, the CAVEME Code of Conduct allows the dissemination of scientific information of an unauthorised product, even through general media, provided the name of the product is not mentioned and provided this information is not intended to promote or advertise the treatment.

Regarding off-label information, there is no specific regulation in Venezuela on that matter. However, any information relating to the product must be consistent with the marketing authorisation and the label approved by the competent authority.

**2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.**

A press release issued by the company that is developing the product might be construed as promotional material of an unauthorised product and hence would be a prohibited practice under local regulations.

Also, a press release issued by the manufacturer or distributor of an authorised product on off-label information would also be construed as promotional material that breaches the law because it is not consistent with the marketing authorisation for the product.

**2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?**

Information of an unauthorised product can be sent to a specific healthcare professional, if he or she request it. However, this information must be shared only for scientific purposes and cannot be intended to promote the product. It cannot mention the product, only the molecule or treatment.

Off-label information of an approved product can also be sent to healthcare professionals, but it must be compliant with the approved marketing authorisation and the label of the product. It does not need to be previously requested by a healthcare professional.

**2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?**

Venezuela does not have a similar provision in its legislation.

**2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?**

No, this information cannot be sent until the product has been authorised for commercialisation in Venezuela.

**2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

No, the company cannot share any information on a product that has not been authorised, except for scientific purposes and with the condition that the product is not mentioned in the information shared with the healthcare professional.

## 3 Advertisements to Healthcare Professionals

**3.1 What information must appear in advertisements directed to healthcare professionals?**

In general, the advertisement for the healthcare professional for prescription drugs must include: (a) the name of the product; (b) the name of the active substance; and (c) the name, address and telephone number of the manufacturer or distributor. Moreover, when printed advertisement material refers to published scientific studies, proper citation of such studies must be included.

**3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?**

The Norms for the Advertisement and Promotion of Pharmaceutical Products establish that when the nature of the scientific information allows for the comparison between different drugs, this can only be made by using the generic denominations and never the registered patents or brand name, including the name of the advertised product.

The Norms also establish that companies can promote through "remainder advertisements" which must at least indicate a simple statement of uses to signal the therapeutic category of the product. The prescription information can be omitted under the condition that the advertisement includes a phrase indicating that additional information is available by request to the healthcare professional.

The legal framework does not regulate if the advertisement may refer to studies not mentioned in the SmPC. However, the Norms establishes that any information on the advertised product must be supported by corresponding bibliographic sources and that it must be consistent with the marketing authorisation.

**3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?**

There are no specific restrictions in this regard in the legal norms. However, the self-regulated norms of the medical profession might establish limits on this matter.

**3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?**

This aspect is not specifically regulated under Venezuelan laws. Restrictions regarding comparative claims in scientific materials can only be made by using the generic denominations and never the registered patents or brand name, which includes the name of the advertised product.

**3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?**

Negative comparative advertisements are not allowed. However, promotions based on price comparisons are permitted.

**3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?**

There are no specific rules governing this issue in the legal norms nor in the self-regulatory standards of the industry. However, if the distribution of such material is intended for promotional purposes, it must comply with the legal framework for the promotion and advertisement of medicinal products.

**3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?**

Teaser advertisements are not specifically regulated under the legal framework applicable to pharmaceutical products. However, the fact that remainder advertisements are regulated (see question 3.2) and impose an obligation to at least include a simple statement of uses to signal the therapeutic category of the product, might indicate that for teaser advertisements, at least such indication must be included too.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

The promotion of off-label uses is not permitted under Venezuelan regulations. Both Product A and Product B must have their SmPCs authorised before health authorities to use in combination with each other before they can promote such use.

## 4 Gifts and Financial Incentives

**4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?**

Yes, it is possible to provide a healthcare professional with samples of medical products.

The Norms for the Advertisement and Promotion of Pharmaceutical Products establishes that the distribution of free samples of prescription medicines to healthcare professionals is allowed, provided it is a consequence of the visit by the medical representative of the manufacturer or distributor of the product and its main purpose is to familiarise the professional with the product. Also, the CAVEME Code of Conduct establishes that free samples may be provided to health professionals if they are identified as such and their sale is restricted.

**4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

The Norms for the Advertisement and Promotion of Pharmaceutical Products establishes that the promotion of products through the granting of financial or material incentives (e.g. money or gifts) is prohibited.

On the other hand, the CAVEME Code of Conduct establishes the same restrictions and specifically prohibits any money or gifts for personal use such as gift cards, music CDs, DVDs, tickets for concerts, etc.

The CAVEME Code of Conduct does allow for the granting of promotional material of low value that is related to the improvement of care for the patient. Also, it allows the granting of articles for medical use, provided it does not interfere with the commercial relations and improves the care for the patient.

Promotional articles cannot have a value higher than five tax units, while an article for medical use cannot be valued over 15 tax units. Please be aware that as of the date of the drafting of this article, a tax unit is equal to approximately US$ 0.01.

**4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.**

The Norms for the Advertisement and Promotion of Pharmaceutical Products establishes that the promotion of products through the granting of financial or material incentives (e.g. money or gifts) is prohibited for both healthcare professionals and any person entrusted with the delivery of medicines. Although, the Norms do not specify whether healthcare organisations are included in this prohibition, health authorities can object to such donations under this prohibition.

**4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?**

The Norms for the Advertisement and Promotion of Pharmaceutical Products establishes that the promotion of products through the granting of financial or material incentives (e.g. money or gifts) is prohibited for both healthcare professionals and any person entrusted with the delivery of medicines because it can induce the prescription or sale of medicines. Hence, although the provision of medical and educational services is not expressly prohibited, if it can encourage a change in the prescription pattern, it could be deemed a restricted practice.

**4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?**

Both the special norms on the advertisement of pharmaceutical products and the self-regulatory standards have not addressed this situation. However, under the antitrust regulation, volume-related and early payment discounts and other usual similar commercial practices are allowed.

**4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?**

Neither the special norms on the advertisement of pharmaceutical products nor the self-regulatory standards have addressed this situation. However, the offer to pay or provide for medical services and equipment in favour of an institution in exchange for the purchase of medical products can be construed as a commercial bribery under antitrust regulations.

On the other hand, the purchase of a medicine linked to the provision of additional benefits might be allowed provided this is a customary contractual benefit offered by other competitors in the industry.

**4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?**

Neither the special norms on the advertisement of pharmaceutical products nor the self-regulatory standards have addressed this situation. However, consumer rights regulations established in the Organic Law of Just Prices (2015) determines that consumers are entitled to return goods that they did not find satisfactory or that have caused damage to the consumer. Hence, a refund scheme is also an obligation, though there are no specific norms that regulate such schemes for either prescription or OTC products.

**4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?**

Yes, in accordance with the Norms for the Advertisement and Promotion of Pharmaceutical Products, companies can sponsor scientific and educational activities provided that such sponsorship is of public knowledge and the company does not interfere with the scientific truth or the freedom of opinion of the participants. The company can mention the sponsorship through the brand of one of its products.

**4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Anti-bribery rules are established in the Law Against Corruption (2014). The norms are set to protect the public patrimony and regulates the interaction of private parties and public officials that might endanger public resources through corrupted practices. However, the Law also includes a general anti-bribery provision that prohibits the offering to any organisation (corporation, not-for-profit entity, etc.) of any benefit in exchange for favouring the offeror in a sale or purchase of any type of product, the punishment of which is an imprisonment of two to six years. Other rules that might be relevant are those regarding the offer to a public official of any benefit of exchange of an advantage in dealings with the public administration (e.g. procurement of goods and services to any public entity), which is also punished with imprisonment.

Said rules are applicable to any representative of the pharmaceutical industry that violates such norms. However, the only liable person would be the individual committing these crimes. There is no corporate liability for the company.

On the other hand, the public prosecutor exercises the enforcement of anti-bribery rules and does not have powers to enforce the laws on the promotion of medical products. Such power only resides with the Ministry of Health. Hence, there is no connection between these two legal frameworks. However, it is possible that during an anti-bribery investigation, a violation of the laws on the promotion of pharmaceutical products may arise, and the public prosecutor can raise such fact to the Ministry of Health. Also, the contrary case may also occur, and the Ministry of Health can submit its findings to the public prosecutor.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

There are no legal regulations regarding the hospitality of healthcare professionals. However, the CAVEME Code of Conduct establishes that the hospitality of healthcare professionals is only allowed in connection with the attendance of educational or scientific events (please see question 5.2).

**5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?**

The CAVEME Code of Conduct allows for the payment of attendance to a scientific meeting. The company must: (a) avoid paying for events that are held abroad, unless it is justified from a logistics and safety standpoint; (b) the event cannot be held in a luxurious facility; (c) accommodation and food expenses must be only paid for the attendee not any of his or her guests and must also be moderate and reasonable; (d) the company cannot finance any social activity; (e) the company can pay for the registration of the event; (f) the attendee cannot be paid for the time invested in the event; and (g) the sponsorship cannot be subject to any condition (e.g. recommend, prescribe or supply a pharmaceutical product).

**5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?**

According to the legal framework, the company will be responsible for communicating the sponsorship of the event to the public and for not interfering with the scientific truth and freedom of opinion of the participants. The company will also be responsible for assuring that any hospitality arrangements being paid by it, would be construed as a material or financial incentive for healthcare professionals for promotional purposes. Hence, the company cannot be held responsible for any other matter before the health authorities.

The breach of self-regulatory standards established in the CAVEME Code of Conduct might be subject to investigation procedures and possible sanctions by such trade association.

**5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?**

The CAVEME Code of Conduct allows for healthcare professionals to be paid to provide expert advice. The following conditions apply to these agreements: (a) there must be a written agreement that includes the bases for the payment of services; (b) the agreement must specify the need for the services; (c) the professional must have the expertise to carry out the activities for which it is being hired; (d) the amount of professionals hired must be proportionate to the need they will resolve; (e) the hiring of the professional cannot be subject to the conditions of recommending, acquiring or prescribing a pharmaceutical product; and (f) the payment must be reasonable and reflect the market value of the service.

**5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?**

The CAVEME Code of Conduct allows for healthcare professionals to be paid to participate in any kind of clinical study, including post-marketing surveillance studies, provided it is subject to the conditions established for the hiring of any professional healthcare expert (see question 5.4 above).

**5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?**

The CAVEME Code of Conduct allows for healthcare professionals to be paid to participate in market research studies, provided it is subject to the conditions established for the hiring of any professional healthcare expert (see question 5.4 above).

## 6 Advertising to the General Public

**6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?**

Yes, in our legal system it is possible to advertise non-prescription medicines to the general public.

The following restrictions apply: (a) unfair competition is prohibited; (b) claim benefits are supported on untruthful bases; (c) the term "innocuous" cannot be used in relation to the use of the medication; and (d) the term "quality" cannot be used in relation to the characteristics and properties of the medicine. Also, some other standards are discussed in question 1.2.

**6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?**

No, it is not possible to advertise prescription-only medicines to the general public in Venezuela.

**6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?**

Yes, the Norms for the Advertisement and Promotion of Pharmaceutical Products allows pharmaceutical companies to sponsor disease prevention awareness campaigns. The Norms do not specify any particular restriction in this regard.

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

A press release on an authorised medicine issued to a non-scientific journal might be construed as promotional material intended for the general public, which might breach the laws on this matter. Hence, a case-by-case analysis of this situation would be more appropriate.

A press release issued by the company that is developing the product might be construed as promotional material of an unauthorised product and hence would be a prohibited practice under local regulations (as we previously mentioned in question 2.3). Also, a press release as unauthorised indications would also be prohibited, it would be construed as promotional material disseminating information that is not consistent with the marketing authorisation.

**6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?**

If the corporate brochures and annual report are intended for shareholders, the local regulation does not establish any restriction on this matter. In fact, the CAVEME Code of Conduct expressly allows for the conveyance of this information to shareholders or for when the laws impose such obligation.

In the case where the information is targeted for promotional purposes, the information is subject to the restrictions discussed in this article.

**6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?**

This issue is not regulated in the legal norms, but instead the CAVEME Code of Conduct establishes some principles on this matter.

The Code determines that the company must comply with the following in their interaction with patient organisations: (a) the nature and purpose of the support provided by the company, as the funding must be documented; (b) the company cannot demand to be the only donor of the patient organisation; (c) funding to patient organisations' events is allowed provided the purpose of these events is educational, professional, scientific or intended to support the mission of the organisation; and (e) meetings with patient organisations must be in adequate locations for the purpose of the event and the food provided by the company must be modest.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Our regulations do not specifically address the provision of benefits directed to patients. The general principle is that the promotion and advertising of drugs in the form of financial or material benefits in favour of health professionals or the person entrusted with the delivery of medicines is prohibited, as it can induce the prescription of the manufacturer's or distributor's drugs.

In this sense, as we previously discussed, the CAVEME Code of Conduct has determined that some items for the benefit of patients can be granted to healthcare professionals (please see question 4.2) and are not considered to be material or financial incentives.

## 7 Transparency and Disclosure

**7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?**

No, there is no obligation for companies to disclose the details of ongoing or completed clinical trials. The promotion and advertisement of the clinical trials must be authorised by the Review Board of Pharmaceutical Products.

The CAVEME Code of Conduct determines that if the company wishes to disclose the details of the clinical trials, it must do so under the strict protection of personal privacy, intellectual property and contractual rights, as well as with adherence to existing legislation and practices at the national level.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

No, our legislation does not require companies to make available to the public information on the value transfers they provide to health professionals, healthcare organisations or patient organisations.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

No, self-regulatory standards do not require companies to make available to the public information on the value transfers they provide to health professionals, healthcare organisations or patient organisations.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

As discussed in questions 7.2 and 7.3, disclosure of value transfers is not compulsory.

## 8 The Internet

**8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?**

There are no specific rules for Internet advertisement and promotion; hence all the restrictions and regulations set forth in the general rules that regulate promotion activities of pharmaceutical products are applicable.

**8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?**

This matter is not regulated.

**8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?**

This matter is not regulated.

**8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?**

Since the definition of promotional material is broad and includes any type of information disseminated by the manufacturer or distributor of a product, this might also include information on the company's website. Hence, such information must be compliant with the restrictions on general promotional information discussed in this chapter.

**8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?**

No, there are no specific rules, laws or guidance for the use of social media. Social media content must be compliant with the general rules applicable to any promotional material.

## 9 Developments in Pharmaceutical Advertising

**9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?**

There have not been any significant developments in relation to the rules related to pharmaceutical advertising in the last year.

**9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?**

Venezuela is currently going through a political and economic crisis that might result in a change of government. A new government might begin a process of restructuring all the legal norms of the country, including those related to pharmaceutical products. Thus, there might be new priority rules subject to revision before those mentioned in this chapter. Hence, we do not expect any relevant development until at least two years after a change of government has occurred.

**9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

There are no general practices or compliance trends that have manifested during the last year.

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